DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
Audie L. Murphy Memorial Veterans Hospital Division
7400 Merton Minter Boulevard
San Antonio, TX 78284

In Reply Refer To: 671/00

Association for Assessment and Accreditation
of Laboratory Animal Care, International
5205 Chairman's Court, Suite 300
Frederick, MD 21703

Distinguished Members:

SUBJECT: 2018 Program Description – AAALAC File #VA-063

Enclosed is the Program Description for this facility's Animal Care and Use Program, as requested in preparation for the 2019 Site Visit, which describes all aspects of the Animal Care and Use Program (policies, animal housing and management, veterinary care, and facilities).

This Facility is requesting no Special Requirements for this visit. For additional information or arrangements, the following AAALAC International contact information is provided for this Institution: (b)(6) va.gov. In the event the designated AAALAC Contact is not available, a secondary telephone contact in Research and Development Office at (b)(6)

Sincerely,

(b)(6)

Enclosure:

AAALAC Program Description

Program Description
Animal Care and Use Program

South Texas Veterans Health Care System
Audie L. Murphy Division

Department of Veterans Affairs

7400 Merton Minter Blvd.
San Antonio, TX 78229

December 2018

For
AAALAC International

Table of Contents (Page numbers need to be checked in the end)

Appendices

Program Description

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

Veterinary Medical Unit (151)
South Texas Veterans Health Care System (STVHCS)
Audie L. Murphy Division
Department of Veterans Affairs

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

The STVHCS is a quaternary care facility, which is affiliated with the University of Texas Health San Antonio (UTHSA). As a Level II Research Facility, STVHCS has more than 355 projects in areas such as aging, cardiac surgery, cancer, Post-Traumatic Stress Disorder, Alzheimer's, and diabetes. Most research and testing, involving human patients, continue to be based on the results of animal experimentation to provide hope for Veterans suffering from diseases that currently lack cures or effective treatments. VA actively supports the use of animals in research, teaching, and testing. The use of animals in VA Research is a privilege granted with the understanding and expectation that such research is conducted according to the highest ethical and legal standards.

C. Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

Guide for the Care and Use of Laboratory Animals, Eighth Edition
VHA Handbooks 1200.07 and 1200.08
Guide and PHS Policy for all animals
Animal Welfare Act regulations for covered species

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publicly available, provide the titles and names; for individuals whose information is not publicly available, you may provide titles only.), and degree (if applicable) of each individual at the level of (b)(6) or above. Names of animal care staff below the title of (b)(6) need not be included, but the titles and number of animal care personnel under each (b)(6) should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

The STVHCS Director is the Institutional Official (IO). Research Service falls under the Chief of Staff who reports to the Director. The Associate Chief of Staff (ACOS) for Research reports to the Chief of Staff. The IACUC/OB Members are appointed by the IO and are aligned under the ACOS/Research. A Veterinary Medical Consultant (VMC) is contracted to provide oversight of the Veterinary Medical Unit (b)(6) provide training and support for (b)(6) (b)(6) and (b)(6) Technicians.

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

(b)(6) Director/IO
(b)(6) Chief of Staff
(b)(6) ., Associate Chief of Staff, Research Service
(b)(6) Deputy ACOS, Research Service
(b)(6) MA, IACUC Administrator
(b)(6)
(b)(6) (b)(6)
(b)(6) Chairperson, SRS/IBC
(b)(6) Industrial Hygienist, Facility Safety
(b)(6) MHP, Radiation Safety Officer, SRS/IBC

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

Current Research Studies include studies in Alzheimer's Disease, Traumatic brain injury, Parkinson's Disease, Cardiovascular Disease, Aging, Fatty liver disease, Post Traumatic Stress Disorder, Kidney Disease, Cancer, Blood disorders and Diabetes.

Principal investigators: 29; Active Protocols: 53

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

Department of Veterans Affairs; Foundation for Advancing Veterans' Health Research; National Institute of Aging; American Heart Foundation; National Institute of Health; Junior Diabetes Foundation; National Institute on Arthritis and Musculoskeletal and Skin Diseases; American Federation of Aging Research (b)(6) Fund; National Institute of Diabetes and Digestive and Kidney Diseases; National Institute of Dental and Craniofacial Research; National Institute of Allergy & Infectious Diseases; National Heart, Lung and Blood Institute; Department of Defense

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
Note: Questions regarding this section should be forwarded to the AAALAC Office.

STVHCS does not outsource animal care. However, since STVHCS and the UTHSA are within the same medical complex, and, most staff have dual appointments, several VA-funded investigators are housed at UTHSA and therefore use their facility to house research animals. The UTHSA Animal Care and Use Program is fully accredited by AAALAC.

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the

institution does not contract for animal care facilities or services, so note.

STVHCS contracts with UTHSA for Veterinary Support. See Item H for additional clarification.

J. Note other relevant background that will assist reviewers of this report.

N/A

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [*Guide*, pp. 13-15]

a. The Institutional Official [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The IO is provided a copy of the Semi-Annual Facility Inspection and IACUC Program Review a week in advance of face-to-face meeting with IACUC Members. Attendees at this meeting include IACUC Chair and/or Vice Chair, Veterinarian, ACOS and Deputy ACOS/Research, and IACUC Administrator. Discussion topics include the findings of the recent Semi-Annual Facility Inspection, IACUC Program Review, and status of facility work orders. Outstanding Work Orders are discussed for immediate resolution. The Director also reviews and approves annual regulatory reports.

b. Role of the Attending Veterinarian [*Guide*, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:
- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.

Note: If preferred, this information may be provided in a Table or additional Appendix.

STVHCS initiates a service contract with the affiliate's Veterinary personnel. The Statement of Work (SOW) includes bi-weekly animal health checks to insure adequate health care is being afforded to all laboratory animals and recommend necessary medical treatment, where appropriate. The service provider uses sentinels to ensure animals and their environment are pathogen free and healthy, hygienic conditions are maintained; access to food and water is convenient; temperature, humidity, illumination, and ventilation are adequate; and approved euthanasia procedures are employed. Additionally, the veterinary medical consult (VMC) will be required to perform a hands-on evaluation of all laboratory animals deemed to have ailments by (b)(6) Personnel. Upon evaluation of ailing animals, the VMC will provide the (b)(6) (b)(6) a Statement of Care for all ailing animals and a list of medications needed for treatment. The VMC will be required to perform duties as the Attending Veterinarian for the STVHCS' Institutional Animal Care and Use Committee (IACUC), the Subcommittee for Research Safety (SRS), and Institutional Biosafety Committee (IBC). These Committees meet on a monthly-basis. Dr.(b)(6) and Dr.(b)(6) are contracted veterinarians who advise, oversee, and conduct disease detection and surveillance, prevention, diagnosis, treatment, and resolution. The VMC also monitor and advise on handling and restraint of laboratory animals, methods of euthanasia, surgical and postsurgical care, promotion and monitoring of animal's physical and psychological well-being, and adequacy of husbandry program. The VMC are routinely involved in the review and approval of all animal care and use protocols, e.g., via a secondary role on the IACUC. Additional responsibilities include training institutional staff in the care and use of laboratory animals; assisting in the establishment and/or monitoring of Occupational Health and Safety Program; monitoring zoonotic diseases; advising and monitoring biohazard control policies and procedures relevant to Animal Care and Use Program.

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.
Note: If preferred, this information may be provided in a Table or additional Appendix.

The (b)(6) is staffed with (1) (b)(6) (b)(6) and three Biological Science Laboratory Technicians (BSLT). (b)(6) Technicians are responsible for all daily animal care, e.g., feeding, bedding changes, water, and general animal room maintenance, euthanasia, animal health checks, assisting in surgical procedures, when needed, and operating anesthesia equipment.

c. Interinstitutional Collaborations [*Guide*, p. 15]
Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

A Memorandum of Understanding (MOU) between the STVHCS and UTHSA is used to define responsibilities of each facility in the animal care program, ownership and oversight responsibilities. This MOU affords a sharing agreement for reports and information pertinent to each IACUC administrative process.

2. Personnel Management

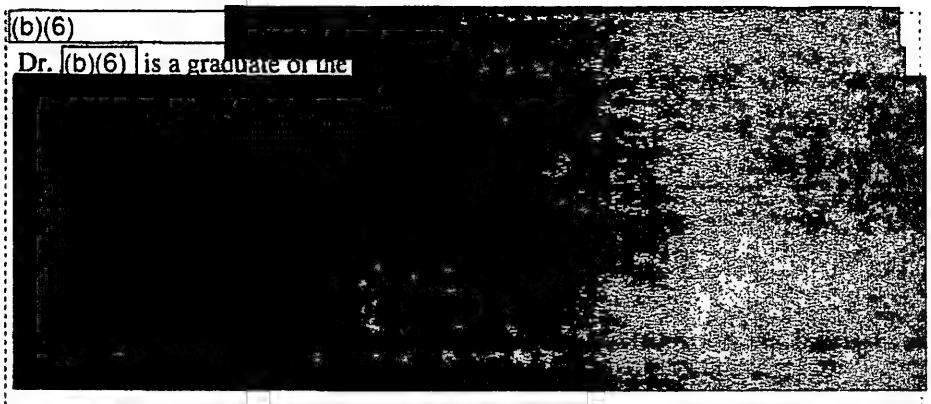
a. Training, Education, and Continuing Educational Opportunities
Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.
Note: Do not include details about the training program, which should be described in the following sections.

Collaborative Institutional Training Initiative (CITI) Training is composed of online modules and quizzes each animal user must review and complete prior to being listed as personnel using animals on an IACUC approved protocol. The topics include an overview of the law and regulations regarding the use of animals in laboratories; working with the IACUC; species specific behavior, handling and procedural guidelines. The IACUC Administrator is also a CITI Administrator who is electronically notified when personnel complete required training. All modules are renewable biennial with the exception of Biosecurity which is indefinite. The IACUC Administrator maintains a separate animal personnel Access database to provide quick access of "671 South Texas Veterans Health Care System" training requirements and/or currency. CITI notifies the individual users 90 days from expiration, while the training coordinator contacts the researcher when they are within 30 days of expiration.

i. Veterinary and Other Professional Staff [*Guide*, pp. 15-16]
For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.
Note: Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

(b)(6)

Dr. (b)(6) is a graduate of the

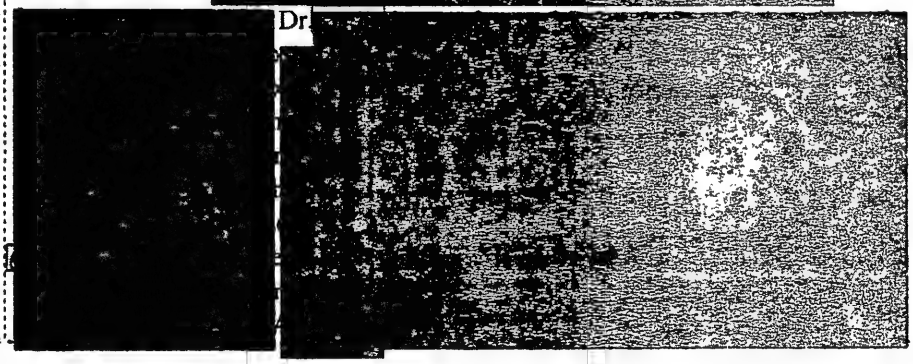


(b)(6)

Consultant: Dr

(b)(6)

Dr.



II. Animal Care Personnel [*Guide*, p. 16]

1) Indicate the number of animal care personnel.

(1) (b)(6) (b)(6) (3) Biological Science Laboratory Technicians (Animal)

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.

Note: If preferred, this information may be provided in a Table or additional Appendix.

(b)(6) (b)(6)

[redacted]

Experience: (b)(6) (b)(6)

[redacted]

Staff:

[redacted]

iii. The Research Team [*Guide*, pp. 16-17; 115-116; 122; 124]

1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

The (b)(6) (b)(6) provides New Employee Orientation, which includes a tour of the (b)(6) New Employees are familiarized with the (b)(6) Operating Procedures, such as room access, lab sign-up and usage, proper clothing, PPE, animal transfers, and, the (b)(6) forms in use. All personnel involved in the care and use of animals participate in the CITI web-based animal care and use training every three years. Employee training status is verified prior to new and continued protocol approvals by the IACUC. All Research Personnel are required to take the course "Working with the VA IACUC" as well as those courses pertinent to the type of research being conducted, e.g., "Working with Mice in Research Settings, Working with Rats in Research Settings, Post-Procedure Care of Mice and Rats in Research". Many of the research investigators and their staff have joint appointments with UTHSA. All faculty, technicians, graduate students, animal technicians and other personnel working with research animals who are also UTHSA employees are also required to

participate in the training program at UTHSA, which includes CITI web-based courses.

a) Briefly describe the content of any required training.

Investigator(s) must certify new personnel has been trained on all the animal procedures that he/she will be expected to conduct and that he/she has verified the employee's competency in accomplishing the techniques. Staff using isotopes are required by Radiation Safety Office to complete Radioisotope Users Training conducted by the VA Radiation Safety staff before being granted approval for radioisotope use. Investigator(s) working with hazardous materials instruct research and animal technicians on protocol specific handling techniques and proper disposal. The (b)(6) (b)(6) provides orientation, information, and policies to all new personnel. Investigators and their technicians performing surgery on any animal are required to complete CITI Post Procedure training. There are also animal use training classes offered to investigators for species and protocol specific procedures by the affiliate university UTHSA. As most of the investigators and research personnel are affiliated with the VA and UTHSA, these classes are available to them. (b)(6) AS, RLAT is responsible for coordination of training sessions and collection of participant documentation from instructors of the training sessions. Optional training class availability is described to all animal research personnel during the INTRODUCTION TO DLAR mandatory training, and during one-on-one interactions between the Department of Laboratory Animal Resources (DLAR) veterinary staff and investigator personnel. Course enrollment is accomplished through direct contact with the DLAR veterinary technicians. The following classes are available:

1. BASIC HANDLING AND RESTRAINT: RODENTS (LEVEL 0)
This course provides basic mouse or rat handling skills. Basic manipulations that may be taught include: 1) restraint for IP or SQ injections, and 2) ear tag application.

2. ASEPTIC SURGICAL TECHNIQUES (LEVEL 1)
Prerequisite: Basic Handling and Restraint (either rodent or non-rodent).
This course provides hands on instruction related to: 1) animal and instrument preparation, 2) appropriate PPE attire, and 3) other aspects involved in performing appropriate aseptic surgical techniques. The content of this course can be tailored to address the learner's needs and species/protocol specific surgical technique issues.

3. ANESTHESIA (LEVEL 2)
Pre-requisite: Aseptic Surgical Techniques.
This course provides training on: 1) various types of anesthesia, 2) scavenging systems, 3) record keeping, 4) animal monitoring during anesthesia, 5) intubation, and 6) post-operative monitoring/recovery. The

content of this course can be tailored to address the learner's needs and species/protocol specific anesthesia issues.

4. RODENT TELEMETRY/DEVICE PLACEMENT (LEVEL 3)
Prerequisite: Anesthesia:
This course provides training on the proper approach and placement of rodent telemetry/devices and mini-pumps. The content of this course can be tailored to address the learner's needs and species/protocol specific device issues.
5. RODENT BASIC SURGERY (LEVEL 3)
Prerequisite: Anesthesia.
This course covers the basic approach, technique, pain management, and post-operative care of common or basic rodent surgeries. The content of this course can be tailored to address the learner's needs and species/protocol specific surgical issues. Examples of specific techniques that may be provided include castration, vasectomy, ovariohysterectomy (OVH), hysterectomy, laparotomy, or orthotopic tumor implantation.
6. BASIC RODENT METHODOLOGY (LEVEL 1)
Prerequisite: Rodent Basic Handling and Restraint.
This course is intended to provide further training on an expansion of techniques that may include: intraperitoneal (IP), subcutaneous (SQ), or intradermal (ID) injections, as well as common blood collection techniques. The content of this course can be tailored to address the learner's needs and species/protocol specific rodent techniques.
7. ADVANCED RODENT METHODOLOGY (LEVEL 2)
Prerequisite: Basic Rodent Methodology (Level 1) and Anesthesia (if applicable)
This course entails more specialized basic rodent procedures requiring a greater level of skill. Examples may include: 1) gavage, 2) technically difficult blood collection methods, 3) IV injections, and 4) subcutaneous tumor injections/implantations. The content of this course can be tailored to address the learner's needs and species/protocol specific advanced rodent techniques.
8. RODENT BREEDING AND COLONY MANAGEMENT. (LEVEL 1)
Prerequisite: Rodent Basic Handling and Restraint.
This course includes a general overview of effective colony management including: 1) record keeping, 2) weaning, 3) basic information on pregnancy and mating, 4) sexing, identification methods, 5) culling, maintaining the appropriate cage density, and 6) trouble shooting. The content of this course can be tailored to address the learner's needs and species/protocol specific rodent breeding and colony management.

b) Describe the timing of training requirements relative to the commencement of work.

(b)(6) (b)(6) provides Orientation Training during personnel in-processing. CITI Animal Training must be accomplished and verified by the IACUC Administrator prior to participation in VA IACUC approved animal research projects. Personnel are required to revisit CITI training modules every three years. Principle Investigators are notified when personnel allow training to lapse and are removed from the project until training is current.

c) Describe continuing education opportunities offered.

Animal handling and specific procedures are provided by (b)(6) (b)(6) and Laboratory Animal Technicians, Veterinarians, and or affiliate university Department of Laboratory Animal Resources (DLAR) Staff. Research personnel are also provided continuing education opportunities for species and protocol specific procedures through the affiliate University as many investigators and technicians have dual appointment at the University. All VMU personnel are active registrants in the AALAS Learning Library.

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

Principal investigators are responsible for ensuring that personnel on their protocol have necessary experience/training to perform surgical procedures and verify the training of their personnel in the Animal Component of Research Protocol (ACORP) Appendix 5 which is reviewed and approved by the IACUC and the Attending Veterinarians. In addition, the veterinarians will perform on-site inspections of ongoing surgical procedures during health rounds. IACUC semi-annual inspection teams may also observe and question the researchers performing surgical procedures during their inspection rounds.

3) Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

Anesthesia can be performed by the VMU Technicians and/or Research Assistants with known experience in anesthesia techniques. Most training is accomplished through on-the-job training or through continuing education.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

Euthanasia can be performed by VMU Technicians and/or research investigators and their Assistants with known euthanasia experience. VMU Technicians have had extensive on-the-job training by the (b)(6) (b)(6) in euthanasia techniques. The PI provides training to ensure that all personnel carry out euthanasia procedures appropriately. Research personnel are periodically monitored by the (b)(6) (b)(6) for appropriate technique.

b. Occupational Health and Safety of Personnel [*Guide*, pp. 17-23]

i. Institutional Oversight [*Guide*, pp. 17-19]

1) List the institutional entities (units, departments, personnel, *etc.*) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g., remote offices to which personnel must report).

The STVHCS Occupational Health Clinic: oversees and administers the Occupational Health and Safety Program for all STVHCS Research Personnel involved in animal research at STVHCS. Personnel with direct physical contact or routine exposure to live animals, animal tissues or body fluids will participate in a preventive medicine program which includes but is not limited to a baseline review by the occupational health physician (b)(6) and an annual periodic animal exposure questionnaire. The baseline evaluation consists of an Occupational Health Baseline Questionnaire completed by the researcher and a certification page signed by the Supervisor before the researcher makes an appointment with Occupational Health Physician. The baseline questionnaire is provided by the IACUC administrator or available on the Research Service intranet. The Occupational Health Physician meets with

the researcher and discusses potential risks involved in animal-related research conducted by the researcher before signing the certification page. The certification page is returned to the IACUC Administrator for filing and updating the database. Only then, and after completion of other prerequisites, are researchers eligible for full participation in animal research. In addition, the IACUC Administrator emails an annual Periodic Animal Exposure Questionnaire to all researchers who work with live animals in January of each year and a list is sent to the Occupational Health Physician for all personnel actively involved in live animal research. The researcher's questionnaire is evaluated by the Occupational Health Physician. The physician's staff prepares a list of all those that have been seen for periodic evaluation and emails it to the IACUC Coordinator.

The University of Texas Health San Antonio (UTHSA) Occupational Health Clinic: overseas and administers the Occupational Health and Safety Program for all research personnel involved in animal research and working on a VA IACUC-approved protocols at the affiliate university. The researcher provides the completed baseline survey and VA Principal Investigator certificate to the UTHSCSA Employee Health Clinic for evaluation by the nurse. The nurse discusses any concerns and then files the certification after notifying the IACUC Administrator of its completion.

According to the established memorandum of understanding (MOU) between STVHCS and UTHSA, both institutions agree that they share regulatory responsibility and oversight for collaborative animal research and shall cooperate to meet each other's regulatory reporting requirements by providing documents or expertise as needed.

The STVHCS Safety Department (Industrial Hygienists): Hearing conservation; noise level monitoring; anesthesia gas monitoring; eye protection monitoring; Fume Hood/Work Station maintenance

The STVHCS SRS/IBC Committees: proper use, maintenance, and disposal of Biological and Chemical Hazards

The STVHSC Radiation Safety Office: proper use and monitoring of ionizing and nonionizing radiation and radiation producing equipment

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

Studies involving hazardous agents and animals must be reviewed by all appropriate subcommittees of the Research and Development Committee before final approval is given to initiate the study. These subcommittees include the Radiation Safety Committee, the Subcommittee for Research Safety and Institutional Biosafety Committee (includes VMU Supervisor, STVHCS Facility Safety Representative, Radiation Safety Officer, R&D Liaison, Veterinary Medical Consultant, Chemical Hygiene Officer, Research Scientist, Research Service Administrative Officer and Deputy Associate Chief of Staff/Research), as well as the Institutional Animal Care and Use Committee (includes VMU Supervisor, Non-scientist Industrial Hygienist and Statistician, in addition to investigators, Veterinary Medical Consultant, R&D Liaison, Community Representative, Research Service Administrative Officer and Deputy Associate Chief of Staff/Research). These committees assess qualifications and training of personnel, assess potential hazards involved in the agents used, and recommend and approve safeguards. In addition, the Research Laboratory Safety Subcommittee conducts monthly laboratory inspections to ensure cleanliness; proper container labeling of chemicals; proper storage of acids; proper storage of flammables; the availability of PPE, appropriate wear and chemical spill kits; the inspection and maintenance of eyewash stations and chemical showers; and the proper storage and use of sharps containers.

3) Describe methods and frequency of reassessing work-related hazards.

Potential work-related hazards are looked for daily at the VMU. If a potential work-related hazard is noticed, it is reported to the (b)(6) (b)(6) for immediate corrective action. Once the work-related hazard has been eliminated, any instance of harm to Research Personnel is reported to the Research Service Administrative Office and the STVHCS Safety Office for further evaluation. Additionally, during semi-annual inspections, the IACUC also evaluates the work areas for work-related hazards and appropriate action is taken.

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

Any instances of safety-related workplace incidents are immediately reported to the (b)(6) (b)(6) Injured employees are seen at the STVHCS Occupational Health Clinic for treatment during usual business hours or in the Emergency Department after hours. The injured person creates an incident report which is verified and signed by the Supervisor. The (b)(6) (b)(6) and (b)(6) conduct a fact finding, and prepare a report for the STVHCS Safety Office follow-up investigation. Exposure to hazardous agents

is also reported to the supervisor and to the Occupational Health Office when requiring immediate treatment. Ambulatory Researchers must notify their supervisor and then proceed to Occupational Health clinic for physical ailment treatment. If non-ambulatory, the Emergency Department will be notified. Occupational Health Clinic will require supervisor to complete ASIST reporting. Users of radioisotopes and x-ray machines, including animal technicians, wear film badges which are monitored by the Radiation Safety Office. Human Diploid Strain Rabies vaccine is available to personnel via the Outpatient Pharmacy at STVHCS.

ii. Standard Working Conditions and Baseline Precautions
The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection iii*** below.

1) Medical Evaluation and Preventive Medicine for Personnel [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

Principal Investigators and Research Assistants involved in animal research, Veterinarians, and Husbandry Staff are included in the VA's Occupational Health Program. Dual-appointed investigators or technicians are included in the affiliate university's occupational health program. Institutional Maintenance Personnel, with potential animal exposure, are informed of potential hazards prior to entering animal rooms. An educational sheet that informs them of the potential for allergy to animal dander is available in the Research Service office and provided prior to the individual being given access to the restricted Veterinary Medical Unit (VMU) area.

b) Describe provisions for allowing an individual (following completion of individual health and job-related risk assessments) to decline participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.

Note: Do not include names of the personnel

All personnel associated with the animal care and use program are to participate in the medical evaluation program. Personnel who decline to participate in the program are not allowed to work with research animals.

c) Describe provisions for assuring confidentiality of medical information.

Medical records of research personnel are kept in secure filing cabinets within Occupational Health Clinic facilities along with the employee medical files

d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

Per HOSPITAL POLICY MEMORANDUM 151-17-05:
Personnel that have incidental exposure to animal housing areas, such as Engineering or Environmental Management Services personnel, will receive an educational sheet that informs them of the potential for allergy to animal dander. The information sheet, which will be provided by the Research Service office prior to the individual being given access to the restricted Veterinary Medical Unit (VMU) area, will instruct personnel who have pre-existing animal allergies, or who develop allergy symptoms after exposure to the animal housing area, to seek help from the Occupational Medicine physician. Employees with significant pre-existing animal allergies have the option to be counseled as to how asthma and allergies may affect their health. Upon the employee's request, the Occupational Health physician will determine whether the employee needs further intervention.

e) Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

Per the EOH CEOSH Guidebook
http://vaww.ceosh.med.va.gov/01HP/02HP_Guidebooks/03_Collections/04HP_OccupationalHealth/EOH.pdf

Table 6-1: Frequency and Content of Medical Surveillance Examination for Animal Handlers

Type of Animal Medical Surveillance Requirements

Small Animals

- Zoonoses questionnaire annually
- Occupational/medical history annually
- Initial basic physical examination
- Tetanus/diphtheria immunization every 10 years

f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

All VA staff including research personnel who sustain injuries or require emergent medical care afterhours may be seen in the VA Emergency Department. Staff in the ED (i.e. physicians and physician assistants) have the experience and qualifications to respond to animal- or institution-related hazards including, but not limited to, bites, scratches, chemical exposures, and reactive airway disease.

2) Personnel Training Regarding Occupational Health and Safety [*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

Note: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

The (b)(6) (b)(6) provides an orientation to all newly assigned personnel working with laboratory animals and informs personnel about allergies, personal hygiene and potential physical injuries in animal facilities. The (b)(6) also meets with all new investigators before they begin any research work and provides information/policies regarding the safety practices followed at the VA. STVHCS Research Service has a "Occupational Health and Safety for Personnel with Exposure to Research Animals" policy that addresses relevant topics listed in the 'Guide for the Care and Use of Laboratory Animals" to facilitate the provision of a safe workplace and work practices for all personnel engaged in the care and use of research animals. All personnel are required to have a VA-Salaried or Without Compensation (WOC) appointment, which require an initial medical history and medical file established with Occupational Health Clinic which oversees and administers the occupational health and safety program. Based on the responses in the initial and annual animal exposure questionnaire, the Occupational Health physician meets with personnel and discusses the potential risks involved in animal research. The STVHCS Research Service uses the Subcommittee for Research Safety (SRS) to evaluate the use of Personal Protective Equipment (PPE) employed to protect personnel conducting VA IACUC-approved research. PPE includes mask, goggles, gloves, lab coat and or other equipment deemed appropriate by this subcommittee. Additionally, all IACUC protocols are also reviewed by the STVHCS Industrial Hygienist and necessary training is provided to the research personnel based on their research. The principal investigator also provides safety training to their personnel based on the research they are conducting and endorses that they have provided training in the continuing reviews of their safety protocols annually. The PI also encourages employees to contact the Occupational Health Physician for guidance. Optional training classes are also provided by UTHSA DLAR.

3) Personal Hygiene [*Guide*, p. 20; *Ag Guide* pp. 4-5]

a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Protective gear and clothing provided to animal technicians include scrubs, steel-toed work shoes, disposable latex and nitrile gloves, rubber boots, goggles, face shields, hearing protection, P.A.P.R., head covers and shoe covers. Yellow isolation gowns are worn exclusively in all animal rooms. The Subcommittee for Research Safety (SRS) evaluates the use of Personal Protective Equipment (PPE) employed to protect personnel conducting VA IACUC-approved research. PPE includes mask, goggles, gloves, lab coat and or other equipment deemed appropriate by this subcommittee.

b) Describe arrangements for laundering work clothing.

Laundry is processed within the VMU Facility using detergent and disinfectant. The VMU clothes washer and dryer are to be used for the washing of scrubs, lab coats, and isolation gowns.

c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

All personnel are required to wash hands after handling animals and are urged to use Purell after leaving animal rooms. Isolation/surgical gowns are provided for all technicians. All VMU Staff are required to wear surgical scrubs under isolation/surgical gowns. Lab coats are worn over scrubs when leaving the animal facility. Isolation/surgical gowns are never worn outside of the animal facility. Changing facilities are in (b)(6) and (b)(6) Shower facilities are available in (b)(6) and (b)(6)

d) Describe policies regarding eating, drinking, and smoking in animal facilities.

Eating and drinking is limited to the VMU Breakroom, Rm, (b)(6) At no time, will eating and drinking be allowed in the Animal Holding Rooms or the Procedure Rooms. Smoking is not permitted inside the VA Hospital.

4) Standard Personnel Protection [*Guide*, pp. 21-22]

a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

(b)(6) (b)(6) and principal investigators provide training to staff and researchers. The following equipment/procedures are used to protect husbandry staff and researchers: Breakaway lanyards for photo identification cards; height-adjustable change hoods; scissor lift carts for handling water bottles; thermal insulated gloves; carts and racks with locking casters; no recapping of needles; caging and changing procedures which minimize allergen and disease exposure; and ventilated animal racks with outside building discharge

b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

To reduce exposure to allergens, i.e., animal dander and soiled bedding, bioBubble Bedding Dump Stations are used to dump dirty cages and fill clean cages. Animal Transfer Systems/Laminar Flow Hoods are used during cage changing.

c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

BioBubble Bedding Dump Stations are used to dump dirty cages and fill clean cages. Animal Transfer Systems/Laminar Flow Hoods are used during cage changing.

d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

Animal Transfer Stations, Bedding Dump Stations, and Laminar Flow Hoods are certified, annually, by an outside agency.

e) Respiratory Protection

i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

As per the STVHCS Respiratory Protection Program 001A-14-19, a risk assessment is conducted to select the type of respiratory protection required. Respirator protection is readily available. Animal Technicians can don half-mask surgical dust barriers when dumping cages, replacing and adding bedding. 3M Air-Mate Power Air-Purifying Respirators are issued to Animal Technicians to reduce their exposure to animal dander.

ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

If respirators are indicated for use, proper fit testing, training, and maintenance would be conducted by the Hospital Industrial Hygienist.

iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

Selection of appropriate respiratory protective equipment and its function would be assessed by the Hospital Industrial Hygienist.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

VMU SOP 18 describes procedures for the use of Cage Wash.
VMU SOP 19 describes procedures for use of Tunnel Washer.
VMU Personnel are trained, annually, by the VMU Supervisor, by review of the VMU SOPs.

ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: If preferred, this information may be provided in a Table or additional Appendix.

N/A

iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

All motorized vehicles used for animal transport are owned, operated, and maintained by the affiliate UTHSA, DLAR.

g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

Isoflurane exposure is assessed through personal monitors by the Hospital Safety Office. Strict adherence to safety practices for all chemical agents is maintained. F-Air cannisters are used as scavenging systems for all anesthesia machines.

Iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

a) Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

Replication defective recombinant adenoviruses
Associated adenoviruses
Lentiviral vectors (generation 3)
Human bone marrow cells
S. pneumoniae
Mesenchymal stem cells
All biological agents used in the VMU fall under BSL-1 or BSL-2 category

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

Bromodeoxyuridine - carcinogen,
Paraquat -carcinogen
N-nitrosodiethylamine-toxic and probable carcinogen
Formaldehyde-irritant; potential carcinogen
5-fluorouracil-carcinogen
MPTP-neurotoxin

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

No studies being conducted at the VMU

2) **Experiment-Related Hazard Use** [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

Studies involving hazardous agents and animals is reviewed by all the appropriate subcommittees of the Research and Development Committee before final approval is given to initiate the study. These subcommittees include the Radiation Safety Committee, Subcommittee for Research Safety, Institutional Biosafety Committee, as well as the Institutional Animal Care and Use Committee. These committees assess qualifications and training of personnel, potential hazards involved in the agents used, and recommend and approve safeguards.

b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

Studies involving hazardous agents and animal research are reviewed by the Radiation Safety Committee, Subcommittee for Research Safety, Institutional Biosafety Committee, as well as the Institutional Animal Care and Use Committee. Based on the research to be conducted and the policies of the Research Service and the hospital, the subcommittees assess the risk and then together with the PI develop procedures to implement appropriate safety and containment procedures. The committees include the veterinarians, hospital safety office members, industrial hygienist and occupational health physician. Annual review of the protocols, semi-annual inspections by the IACUC and routine checks by the VMU staff aid in ensuring that the procedures to manage the risks are followed.

c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

Disposal of caging and bedding will be handled in accordance with safety procedures approved in the individual protocol. In studies with DEN, animals are injected in laminar flow hoods and then placed in clean cages with regular bedding (TekFresh). Cages are not handled till the next injection of the

animals which is at least 72 hrs later. Dirty cages are left under UV light for at least 48 hours before autoclaving bedding and disposing as non-hazardous waste. Similar precautions are taken for studies with paraquat. Self-sheathing syringes are used which are discarded in approved containers to be disposed of as a hazardous waste through the VA Safety office. Carcasses of animals are refrigerated before being transported to the UTHSA DLAR on an as needed basis for incineration. Radiation safety officer will verify appropriate radioactive decay timeframe in radioactive carcasses prior to disposal. Strict adherence to safety practices for all chemical agents is maintained

d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

All personnel who are exposed to animals, tissues, fluids, or body products are included in the Occupational Health program. The Office of Occupational Health/Occupational Health Physician establishes and coordinates appropriate follow-up, referral, or treatment for each employee. The pre-employment physical includes immunization history review and recommendations for tetanus/diphtheria immunization if indicated. Pre-exposure rabies vaccine is available for high risk employees. Records concerning bite wounds and occurrence of any unusual illness are retained by the facility.

3) Hazardous Agent Training for Personnel [*Guide*, p. 20]
Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

When hazardous agents are in use, VMU Personnel are made aware of the potential hazards by the (b)(6) (b)(6) (who is a member of the IACUC and SRS/IBC), given a copy of the Safety Data Sheet, and provided additional PPE. If needed, additional training is provided by the (b)(6) (b)(6)

4) Facilities, Equipment and Monitoring [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).
Note: If preferred, information may be provided in a Table or additional Appendix.

All animals exposed to hazardous agents are housed in VMU Room (b)(6)

b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

At no time, will animals be housed outside dedicated animal rooms.

c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

No special equipment/facilities are available and animals exposed to hazardous agents are housed separately in VMU Room (b)(6) 1 in conventional caging. Cage cards are properly identified and room doors labeled with hazardous agent signs. Disposal of caging and bedding is handled in accordance with safety procedures approved in the individual protocol by VMU personnel. Isoflurane exposure is assessed through personal monitors through the hospital safety office. Access to infected animals is strictly limited to only Protocol Personnel and VMU Staff, via the Edstrom Watchdog System.

d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

Safety specialists from the hospital safety office are members of the IACUC and the Research Safety Committee to provide safety input to the committees in approving appropriate practices and procedures. The (b)(6) (b)(6) insures that when hazardous agents are in use, the hazards will be displayed on the door of VMU Room (b)(6), along with the Safety Data Sheet. Additionally, PPE which include gowns, gloves, masks, shoe covers will be made available. Personnel requiring the use N95 masks will be trained by the Industrial Hygienist.

e) Incidental Animal Contact and Patient Areas

i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

Animals are not used in patient areas.

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

All transportation of animals and animal equipment is done using the Research dedicated elevator (b)(6) If the Research dedicated elevator is out of service, Hospital Freight Elevators are used. (2) VMU Personnel will accomplish this and will not allow non-VMU Personnel entry to elevator if animals, carcasses, or dirty bedding is being transported.

B. Program Oversight

1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7**.

i. Describe Committee membership appointment procedures.

Committee members are nominated. The standing committee votes on the nomination(s). If approved, new members are appointed by the director for a 3-Year Term. Members may elect to continue their appointments after the conclusion of three-year appointment.

ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

IACUC meets monthly. Infrequently, a special meeting is called if a protocol or other information requires attention between the normal meeting schedule.

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

Members are provided a copy of the IACUC Policy Memorandum. Committee Members must complete *Essentials of the IACUC* training in the CITI Program prior to becoming an Active Member. Additional IACUC Scenario Training is electronically mailed to the IACUC Administrator from the office of the Chief Veterinary Medical Officer (CVMO). This training is emailed to committee members prior to the meeting for familiarization. The veterinarian/DACOS conducts the training at the designated meeting and opens the floor for discussion.

b. Protocol Review [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 9.** Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal use. Include descriptions of how:
- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and
- the use of animals and experimental group sizes are justified.

Note: Make sure you address each of the items above.

[a] All Animal Component of Research Protocols (ACORP) undergo a Full Committee Review (FCR), with 2 IACUC Members designated to review the ACORP prior to presentation to the IACUC. During FCR, the IACUC deliberates and weighs the objectives of the study with the pain and distress that will be experienced by the animals during the course of the experiments (harm-benefit analysis). The ACORP includes a specific section that prompts investigators to seek alternatives to painful procedures during design of research studies and scientifically justify why less painful alternatives will not be used if they are available. The protocol document also instructs investigators to seek technique refinements so that the least invasive/painful/distressful procedures to the animals are used. The investigator must describe physical or physiologic conditions in the animals that define a moribund state and result in an animal being removed from a research study i.e. humane endpoint(s). Protocols also require justification (e.g. power analysis) of the number of animals required to answer the scientific question so that the minimum number of animals are utilized for the research. The IACUC reviews the ACORP and if necessary, appropriate modifications to the protocol are requested prior to the protocol approval so that the benefits of the study (eg. defining new target molecules for disease prevention) outweigh minimal possible pain and distress to the animals.

[b] If issues surface with a protocol and substantive scientific revisions are required, the protocol is tabled by majority vote and a revised protocol is provided to all members for review at the next committee review. If the revisions to the protocol as required by FCR for approval are minor and substantive, the quorum of members present at the convened meeting may decide by unanimous vote to use designated member review (DMR) subsequent to FCR. The specific method of a given protocol is documented in the minutes along with the outcome of the review.

° All ACORPs require Veterinary consultation during the writing of the protocol. The Veterinarian consulted and date of consultation is annotated under the *Veterinary Care and Husbandry* section of the ACORP.
° All Animal Numbers are reviewed by the Research Statistician. A power-analysis is conducted by the Research Statistician and the Investigator so that experimental group sizes are justified and the minimum number of animals are utilized to answer the scientific question.

ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments.
Note: If preferred, this information may be provided in a Table or additional Appendix.

The IACUC requires the investigator to submit a request for modification form that provides complete details of the requested change to the proposal and the effect on other aspects of study/animal component. Any changes in experimental procedures are considered major modifications while personnel changes are minor amendments. Modifications are reviewed by full committee review (FCR) and evaluated using the same criteria as initial review of the animal protocol. If the information provided is complete and meets approval criteria, the modification is approved by the committee. If the information provided is incomplete and substantive revisions are required by the committee, the IACUC withholds approval of the modification until the next full committee meeting when the revised modification is presented again for FCR. If non-substantive revisions are required, the IACUC approves designated member review (DMR) of the revised protocol to confirm the revisions are made as required by FCR. The investigator is then emailed a signed copy of the approval document, allowing them to commence research. During the Third-Year Review of an approved protocol, all amendments and/or modifications must be incorporated.

c. Special Considerations for IACUC/OB Review [*Guide*, pp. 5; 27-33]

i. Experimental and Humane Endpoints [*Guide*, pp. 27-28]

1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

The IACUC requires alternatives to experimental endpoints for animals in a study be developed and described in the written protocol document by the investigator. The protocol document provides a subsection that specifically addresses the plan for animals that become moribund or severely debilitated while on study. It includes individual statements of IACUC policy criteria for early endpoint/euthanasia that must be followed along with an area where the

investigator can request for exceptions to the criteria with appropriate scientific justification.
The descriptions of all experimental and humane endpoints are included in the written protocol and receive IACUC review and must be approved prior to implementation.

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

Studies that do not utilize humane endpoints, e.g., death as an endpoint, require strong scientific justification for IACUC approval. A description of additional monitoring of moribund animals is required and may require frequent or continuous monitoring of moribund animals by the Principal Investigator and/or Staff.
If it is a novel study for which humane endpoints are not known, the IACUC may suggest the use of pilot studies to be designed in consultation with the veterinarian to identify the humane endpoints and results reported to the IACUC.

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

Protocol Staff and VMU Staff are responsible for monitoring animals for potential pain and distress. Appropriate species- and study-specific training will be included in the protocol to be approved by the IACUC before starting the study. Any animals observed in pain or distress are reported, immediately, to the (b)(6). (b)(6) (b)(6) will contact PI and veterinarian, requesting immediate evaluation of animals.

ii. Unexpected Outcomes that Affect Animal Well-being [*Guide*, pp. 28-29]
Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

The IACUC requires more frequent monitoring by the PI Staff and VMU Staff for animals in studies that involve new or unique procedures or animal manipulations that may result in unexpected outcomes. The additional monitoring will be described in the protocol document to include response actions by personnel when unexpected outcomes that affect animal health and well-being are discovered. Additionally, in studies that may result in genetically modified animals of unknown phenotype, the first offspring of the newly generated phenotype would be carefully observed from birth into early adulthood for signs of distress, pain or disease and

reported to the IACUC as number of animals and revision of protocol may be required.

iii. Physical Restraint [*Guide*, pp. 29-30]
Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

When restraint devices are used, they must be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means or to prevent injury to animals or personnel. Restraint devices are not considered normal methods of housing. Restraining devices will not be used simply as a convenience in handling or managing animals. The period of restraining is the minimum required to accomplish the research objectives. Animals subjected to restraint devices are provided training to adapt to the equipment and personnel. Provision is made for observation of the animal at appropriate intervals, as determined by the IACUC. Veterinary care should be provided if lesions or illnesses associated with restraint are observed.

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe
   - the duration of confinement
   - acclimation procedures
   - monitoring procedures
   - criteria for removing animals that do not adapt or acclimate, and
   - provision of veterinary care for animals with adverse clinical consequences.

Note: If preferred, this information may be provided in a Table or additional Appendix.

There have been no studies performed at the VMU during the past three years that utilize prolonged physical restraint.

iv. Multiple Survival Surgical Procedures [*Guide*, p. 30]

Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

> The principal investigator must provide written scientific justification in the protocol document when requesting to perform multiple survival surgical procedures on a single animal. The IACUC deliberates, during protocol review, the necessity of the procedure for accomplishing the scientific goals of the study with the overall impact it will have on the quality of life of the animal post-procedurally. The principal criteria utilized to determine impact is the ability of the animal to perform the basic functions necessary to maintain a relatively "normal" state of well-being i.e., ambulation, thermoregulation, eating, drinking, urination, and defecation.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

Note: If preferred, this information may be provided in a Table or additional Appendix.

> There are currently no studies conducting multiple major survival procedures within the VMU.

v. Food and Fluid Regulation [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

Note: If preferred, this information may be provided in a Table or additional Appendix.

There are currently no studies at the VMU that utilize food or fluid regulation as part of the experiments.
For such studies, animals are weighed every 2 days to ensure that there is no more than 20% loss of weight from baseline. Food/fluid intake and urine/fecal output are monitored daily. In addition, all animals are observed at least daily by study staff for any signs of diseases or physical abnormalities.
VMU Staff also perform subjective health assessments of all animals, daily.

vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

When the PI requests the utilization of non-pharmaceutical-grade drugs, a suitable pharmaceutical-grade compound or its vehicle must not be available and a scientific justification for the use must be provided by the PI in appendix 3 of the ACORP. The investigator completes ACORP appendix 3 that addresses the justification for use of non-pharmaceuticals. In addition, the administrator provides an electronic copy of Research Service Policy Memorandum 13-72, Non-Pharmaceutical Grade Chemical or Other Substances Use to the principal investigator. All requests are reviewed and either approved or disapproved by the IACUC.

vii. Field Investigations [*Guide*, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

N/A

viii. Animal Reuse [*Guide*, p. 5]

1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

N/A

2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

N/A

2) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.

Note: A list of specific protocols involving reuse of animals should be available during the site visit.

N/A

2. Post-Approval Monitoring [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

All animal protocols receive full committee reviews (FCR) by the IACUC annually. At the first and second anniversaries of IACUC approval of a study, the IACUC reviews a local form that provides names of personnel associated with project, changes to animal scope of work, conflict of interest, changes to safety survey, animal use numbers, and a study progress update. A local modification form is submitted to the IACUC for review and approval of any change prior to implementation. Prior to the third anniversary of the protocol, the principal investigator submits a De Novo application to the IACUC, incorporating previous modifications and new procedures for evaluation and approval.

b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

The IACUC conducts Semi-Annual Institutional Animal Care and Use Program Review and Facilities Inspection in June and December of each year. Two voting IACUC members and the Veterinarian are required to participate in the Facility Inspection and Program Review. All other members may accompany the Inspection Team. The UTHSA Office of the Institutional Animal Care Program provides copies of all UTHSA Semi-Annual Facility Inspection and Program Review documentation to the VA IACUC for VA-Funded animal studies that occur at UTHSA Facilities. The Semi-Annual Facility Inspection and Program Review documents are evaluated and approved by a majority of the members at the next convened IACUC committee.

c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

Note: A copy of the last report of these reviews should be included as **Appendix 10.**

The IACUC conducts Semi-Annual Institutional Animal Care and Use Program and Facilities Inspection in June and December of each year. Two voting IACUC members and the Veterinarian are required to participate in the Inspection and Program Review. All other members may accompany the Inspection Team. The UTHSA Office of the Institutional Animal Care Program provides copies of all UTHSA Semi-Annual Facility Inspection/Program Review documentation to the VA IACUC for VA Funded animal studies that occur at UTHSA Facilities.

d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

N/A

e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

IACUC Members or VMU Staff may directly observe animal use procedures and ask questions to personnel performing procedures about protocol requirements and/or facility policies while visiting the VMU or during the Semi-Annual Facility Inspections. IACUC Members may also participate in direct post-approval monitoring of a protocol procedure as part of an investigation of animal welfare or regulatory compliance concern. STVHCS has a Research Compliance Officer (RCO) whose primary responsibility is auditing and reviewing research projects relative to requirements for Laboratory Animal Welfare, Research Safety, and other areas under the jurisdiction of and specified by the VA Office of Research Oversight. In addition to conducting required audits, the RCO may serve as a nonvoting consultant, as needed, to the facility's R&D Committee, IACUC, Subcommittee on Research Safety (SRS), Institutional Biosafety Committee (IBC), and other research review committees.

3. Investigating and Reporting Animal Welfare Concerns [*Guide*, pp. 23-24] Describe institutional methods for reporting and investigating animal welfare concerns.

The IACUC reviews concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: 1) notices to report any misuse of animals is posted throughout the VMU. All allegations of improper animal care and use is reviewed promptly by the IACUC and investigated if warranted. 2) The IACUC Chair is responsible for appointing fact-finding committee members who will report their findings to the entire committee at a convened meeting. If an activity requires immediate

action, the IACUC Administrator will notify the Veterinarian and the IACUC Chair for review. The Veterinarian, or his designee, unilaterally, may decide to euthanize an animal in extreme distress or pain that cannot be alleviated if euthanasia is determined to be in the best interest of the animal. All reasonable attempts to seek advice from the above individuals and the Principal Investigator will be made. The Veterinarian may require an Investigator to cease procedures in process when the Veterinarian determines the animal to be in extreme distress or pain if cessation of work in progress is determined to be in the best interest of the animal. After review, these individuals will agree upon and follow a course of action deemed to be in the best interest of the animals' welfare. A report of the action taken will be provided to the IACUC during a convened meeting. Minor deficiencies discovered through inspections will be corrected on the spot or referred to the VMU Staff for follow-up. Concerns of IACUC Members, Staff, or Investigators are presented to the IACUC for review at the next scheduled meeting. The IACUC minutes will, in all cases, document action taken and include any Minority Opinions. 3) All IACUC related activities including findings, concerns and recommendations are included in the monthly minutes which are routed to the Institutional Official for review and signature. A vote by the committee to suspend a program is routed through the ACOS, Research and Development to the Institutional Official. If the findings indicate significant deficiency that must be reported, the facility will submit the information to all applicable oversight agencies. The animals associated with the Principal Investigator will be assigned to a "hold status" (animals cared for by VMU Staff but no further experiments will be conducted) pending resolution of allegation or euthanized if deemed appropriate.

4. Disaster Planning and Emergency Preparedness [*Guide* p. 35]

Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:

- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

Note: A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

Disaster Planning is coordinated with the Hospital Emergency Readiness Team, Research Administrative Officer, Contract Veterinarian, and the VMU Supervisor. If animals are to be evacuated, the evacuation site is UTHSA, DLAR. First priority will be given to all breeder animals, then, general population as space/time permits.

II. Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

1. Temperature and Humidity [*Guide*, pp. 43-45]

a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.
Note: If preferred, this information may be provided in a Table or additional Appendix.

The HVAC system of the VMU is operated through the Energy Management System located in the (b)(6) Air Conditioning systems are inspected on a quarterly basis. Ventilation rates are inspected on a yearly basis. Temperature and humidity levels of the animal rooms are monitored and recorded, on a daily basis, by VMU Technicians. Additionally, all rooms are monitored, 24/7 by the Edstrom Watchdog System.

b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
Note: If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

Animal Holding Rooms (mice and rats) have temperatures set points at 68° - 74°, with humidity set points at 40%-60%.

c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

Cardboard bedding is used in all animal cages. Additionally, animals are encouraged to be group housed. Singly housed animals are given nesting materials and additional environmental enrichment, i.e., shepherd shacks, tunnel tubes.

2. **Ventilation and Air Quality** [*Guide*, pp. 45-47]

   a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
   Note: If preferred, this information may be provided in a Table or additional Appendix.

   All animal rooms are monitored, 24 hours a day, 7 days a week, for light intensity, temperature, air changes, and, humidity by the Edstrom Watchdog Vivarium Monitoring System. If any room falls outside of acceptable range, the Watchdog System will notify the VMU Supervisor, telephonically. The VMU Supervisor then notifies the Emergency Systems Control Center at the VA to determine course of action to be taken. All records are kept within the Watchdog System. Additionally, animal rooms' temperatures and humidity levels are monitored and recorded by VMU Technicians, daily, during Health Checks.

   b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

   Allentown ventilated cage racks are used to house mice within the VMU. Ventilated racks continuously filter room air in to each cage at a rate of 60 changes per hour. Animal Care Systems, M.I.C.E. racks are used to house all rats. The M.I.C.E. racks are vented using the exhaust of the building HVAC System. Ventilated racks are exhausted via direct connection to the house exhaust system. The Safety Office, in conjunction with Energy Systems, conducts animal room pressure checks annually.

   c. If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

   N/A

3. **Life Support Systems for Aquatic Species** [*Guide*, pp. 84-87]

   a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

   N/A

   b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.

Note: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

N/A

4. **Noise and Vibration** [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

All animal racks and carts, used within the VMU, have rubber wheels and doors to animal rooms are self-closing.

B. Animal Housing (all terrestrial, flighted, and aquatic species)

1. **Primary Enclosures**
Note: A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 13**.

a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

Animals (mice or rats) are housed according to protocol specifications in either Allentown IVC microisolator cages, or, Animal Care Systems M.I.C.E. cages. All animal cages use contact bedding and water bottles. Housing density is determined according to recommendations in the *Guide for the Care and Use of Laboratory Animals*.

b. Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

N/A

2. **Environmental Enrichment, Social, and Behavioral Management** [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

   a. **Environmental Enrichment**

      i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

      Bio-huts, bio-tunnels, and rat huts are used.

      ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

      All animals are housed on deep contact cardboard bedding that promotes nesting. Nestlets are added to breeding cages and singly housed animals. Hard pelleted food promotes gnawing behavior.

   b. **Social Environment** [*Guide*, p. 64]

      i. Describe institutional expectations or strategies for social housing of animals.

      Mice and rats are group housed within a cage to a maximum number based on available floor space per *Guide* recommendations.

      ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

      Principal investigators may request single housing of animals in the protocol document along with a scientific justification for this housing condition. The IACUC reviews all requests for single housing along with the justification during the protocol review process.

      iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

      Singly housed animals have visual and auditory contact with animals in adjacent cages. They are provided with deep bedding material (Tek-Fresh) to encourage burrowing or nest building. Additional enrichment, i.e., nestlets, bio-tubes, bio-huts are given.

c. Enrichment, Social and Behavioral Management Program Review [*Guide*, pp. 58, 69]
Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

Enrichment programs and exception to social housing of animals is reviewed during the Initial IACUC review of the ACORP, Third Year Review and during semi-annual inspection of the facilities.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]
Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

All newly received animals undergo a 3-day acclimation period to provide habituation to new surroundings. There is no specific habituation provided for routine husbandry procedures. A training/habituation period for novel experimental procedures is described in the protocol document.

e. Sheltered or Outdoor Housing [*Guide*, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

N/A

ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

N/A

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

N/A

f. Naturalistic Environments [*Guide*, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

N/A

ii. Describe how food, water, and shelter are provided.

N/A

iii. Describe how animals are captured.

N/A

C. Animal Facility Management

1. Husbandry

a. Food [*Guide*, pp. 65-67]

i. List type and source of food stuffs.

Mouse/Rat diet, #7012, Irradiated feed, Envigo

ii. Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

All feed is stored in a constant temperature room (walk-in refrigerator) at 39°- 41° Fahrenheit, on either bulk carts or pallets. Feed is used on a First In – First Out cycle. Pyrethrins are used for insect control. Wild rodents are controlled by rodent traps and/or a professional, contracted exterminator.

iii. Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

N/A

iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

All feed is provided, *ad libitum*, via stainless steel, wire bar lids. Feed levels are checked on a daily basis during Health Rounds.

v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

All feed is procured from an approved vendor, Envigo, and is stored in the walk-in refrigerator according to type and date of manufacturer. Feed is used on a first in first out rotation. Feed is ordered and delivered on an as-needed basis, to keep inventory small. No feed is stored for more than 3 weeks.

b. Drinking Water [*Guide*, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

The primary water supply for the VMU is from the municipal water supply. Water is provided to animals via water bottles. Water to the bottle filler/proportioner is filtered through 0.2micron filters via reverse osmosis. Deionized water is available as a backup source.

ii. Describe methods of quality control, including monitoring for contaminants.

The water at the VA Hospital is checked monthly by the City of San Antonio for microbiological and clinical contaminants. The pH of bottle filler is continuously monitored during use and calibrated annually.

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

N/A

c. Bedding and Nesting Materials [*Guide*, pp. 68-69]

i. Describe type(s) and how used for various species.

Tek-Fresh (Envigo) bedding is used for all laboratory animals. Tek-Fresh is a pre-consumer, paper product, used as a direct contact animal bedding.

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures.

Autoclaved Tek-Fresh bedding bags are stored, off the floor, on bulk-carts in (b)(6) Repeater Mouse traps are used for vermin control and the area is inspected by staff daily, during their Health Checks.

iii. Describe quality control procedures, including monitoring for contaminants.

Bedding is utilized on a first in first out rotation. Bags are examined for damage when received and when opened for use. Periodic analysis is available from Envigo listing contaminant-monitoring results.

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

The VMU relies on the UTHSA DLAR for transporting of animals to and from the VA.

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

Girton Cage Washer; Northstar Tunnel Washer; Steris Autoclave (2); Edstrom Bottle Filler/Proportioner; Edstrom Watchdog Vivarium Monitoring System

e. Sanitation [*Guide*, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

All animals are housed on contact bedding. Bedding in breeder mice and rat cages is changed on a weekly basis and bi-weekly in non-breeder mice and rat cages.

2) Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

N/A

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

All soiled cages are transported to (b)(6) and then dumped in to waste basket, using a bioBubble Animal Bedding Disposal Unit. After being run through the Tunnel Wash, all clean cages are transported to (b)(to have clean bedding added. Again, a bioBubble Animal Bedding Disposal Unit is used to accomplish this.

ii. Cleaning and Disinfection of the Micro- and Macro-Environments
Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

N/A

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

The temperature of the NorthStar Cage Washer is monitored immediately prior to use by means of Pharmacal Temp-Tapes, 180 degrees. The cage washer effectiveness is microbiologically monitored, bi-annually, using the Charm NovaLum and ATP Swabs. Results are maintained in VMU office. Proper mix/use of cage/tunnel wash chemicals is calibrated/monitored monthly. Calibration/monitoring is performed by a Cani, Inc. technician and results are kept in the VMU Office.

b) Describe preventive maintenance programs for mechanical washers.

Cage and Tunnel Washers are on a service contract with Abbott Medical. Abbott Medical performs routine monitoring of equipment quarterly, and, reports are maintained in the VMU Office. VMU Technicians perform Operator Level Maintenance on a daily basis.

f. Conventional Waste Disposal [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

All soiled bedding is removed in the dirty side of the Cage Wash Room (b)(6) daily. Soiled cages are dumped, using a bioBubble Bedding Disposal Unit, in to a lined plastic garbage can. After all cages have been dumped, full bags are transported to the VA Hospital Loading Dock trash compactor. The final destination of this refuse in the City Landfill.

ii. Animal carcasses.

Animal carcasses are kept in lined garbage cans inside the refrigerator, located in (b)(6) Carcasses are transported and incinerated by UTHSA, DLAR on an as needed basis.

g. Pest Control [*Guide*, p. 74]

i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

Certain non-animal housing areas within the VMU have been targeted for monthly pesticide application. The spraying of pesticides is performed by contracted personnel. Spraying of pesticides is limited to the following areas the Cage Wash Room, Treatment Rooms, Restrooms, Necropsy Room, and the VMU Administrative Office. Repeater Mouse Traps are used in all Animal Housing Areas and are monitored, daily, by VMU Technicians.

ii. Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

N/A

iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

Researchers/Technicians are informed about pesticides and vermin control procedures during their VMU Orientation/Tour. Any deviation in the Vermin Control Program will not be implemented without written approval from the affected investigators or animal users.

h. Weekend and Holiday Animal Care [*Guide*, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

One VMU Technician is scheduled for duty during weekends and holidays from 8:00 a.m. to 12:00 p.m. Primary weekend duties include checking all animals for any signs of disease or distress, removing any dead animals and disposing of properly, maintaining adequate supply of food and water to all species, assisting Research Technicians with procedures and postsurgical care of animals, and sanitizing any dirty cages.

ii. Indicate qualifications of weekend/holiday staff if not regular staff.

N/A

iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

In the event of an emergency, VA Police and the switchboard are instructed to call the VMU Supervisor. Additional personnel (e.g., VMU Staff, Investigators, Contract Veterinarian) are contacted by the VMU Supervisor as needed. Animal Holding Areas have their temperature and humidity levels monitored by the Edstrom Watchdog System. In the event of temperature/humidity issues, Watchdog has been programmed to call the VMU Supervisor or his designated replacement, who in turn, will contact STVHCS Energy Systems personnel.

2. Population Management [*Guide*, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

The primary form of animal identification is the animal cage card. Additional identification methods are tail marking and ear punches. Information contained on cage cards for all species: name of investigator, protocol number, name of contact and phone number, species/strain, sex, date of birth, location, date of arrival, and cage card number.

b. Breeding, Genetics, and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

Researchers use reputable breeders for animal purchases. In addition, Veterinarians are available for advice on animal model selection.

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and sub-strain or the genetic background of all animals used in a study.

There is no formal program for advising investigators on use of standardized rodent nomenclature. However, investigators include all strains and sub-strains that will be utilized in a study in the protocol document and subsequent annual review reports which are reviewed by IACUC Members for accuracy and consistency of nomenclature.

iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Different cage card colors are used for each Investigator. Investigators may choose to use a series of 1/8" and ¼" colored dots to indicate certain strains on their cage cards. When weaning is performed, specific cage card color, colored dots, and strains are listed on the wean sheet.

iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

The process for monitoring, managing and reporting phenotypes that negatively impact animal well-being would be described in the animal use protocol for review and approval by the IACUC. For newly generated genotypes with unknown phenotypes the first offspring of the newly generated phenotypes would be carefully observed from birth into early adulthood for signs of distress, pain or disease and reported to the IACUC as number of animals and revision of protocol may be required. The IACUC will also require more frequent monitoring by the PI Staff and VMU Staff for animals in studies that involve new or unique procedures or animal manipulations that may result in unexpected outcomes. The additional monitoring will be described in the protocol document to include response actions by personnel when unexpected outcomes that affect animal health and well-being are discovered.

III. Veterinary Care [*Guide*, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

VA VMU and VA Researchers procure rodents only from Approved Vendors. An approved VA list of Vendors is provided by the UTHSA DLAR. These Approved Vendors provide routine health surveillance data indicating that their animals are free of certain target diseases. Animals will be purchased from these approved vendors for the VMUs Sentinel Program. Animals from approved vendors must remain free of these target diseases to remain on the approved vendor list.

VA Investigators wishing to use animals from other institutions, must coordinate with the UTHSA DLAR Veterinarians. These animals, if approved, would go through an extensive quarantine period, at UTHSA, prior to their housing within the VMU.

2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

Laboratory animals (rodents) are transported in climate controlled vehicles to the institution in specially designed, opaque, transport cages with passive air filters that maintain biosecurity. They are received at the VA loading dock and delivered to the VMU using a designated elevator (b)(6) Once received by the VMU, laboratory animals are removed from the shipping container to VMU caging in the receiving/acclimation room using an Animal Transfer Station. After acclimation period (3 days), they are moved to a housing room. Housing room selection is determined by Investigator, health status e.g. SPF, and immune status. Animals are transported from housing rooms to procedure rooms within the VMU in the home cage on a cart.

B. Preventive Medicine

1. Animal Biosecurity [*Guide*, pp. 109-110]

a. Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

The VMU has a dirty bedding rodent sentinel program. Two, non-contact sentinel rodents are maintained on one housing rack in each rodent room within the vivarium. A mixture of dirty bedding from a random sampling of cages in the room is added to the sentinel cage at each change out. One sentinel animal in a cage is euthanized quarterly. Mice and rats received directly from the vendor may also be euthanized as part of sentinel testing. All sentinel animals are examined for internal and external parasites. A necropsy is performed and histopathology is done as appropriate. Sentinels and/or vendor mice and rats are examined for antibodies against Mouse Hepatitis Virus (MHV), Sendai virus, PVM, GDVII, MVM/MPV and Mycoplasma pulmonis. Less frequently, Ectromelia titers are determined. Rats are examined for antibodies against Rat Coronavirus (RCV), KRV and PVM, Sialodacryoadenitis Virus (SDA), Sendai virus, and Mycoplasma pulmonis. Histopathology is done if indicated. Helicobacter sp. testing is done on an as needed basis through Sentinel Program. Pinworms and fur mites are tested with a fecal sample or a swab sample quarterly by PCR.

b. Describe methods used to control, contain, or eliminate infectious agents.

If an infectious agent is identified in a colony animal, the entire housing room is put in a quarantine status, i.e. signs posted, limited access, increased use of PPE, until the extent of the infection is determined. All involved investigators are contacted. Treatment, control, and elimination options for the animals are discussed, approved, and initiated. The IACUC will also be contacted with a status report. The room will be maintained in a quarantine status until post-treatment testing results indicate the agent has been eliminated.

2. Quarantine and Stabilization [*Guide*, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

Rodent containers are examined on arrival by the VMU Supervisor and/or a VMU Animal Technician. If container defects are detected, the shipment is rejected. Incoming mice are housed in room (b)(6) and incoming rats are housed in (b)(6) They are observed for gross abnormalities and health problems during transfer to VMU caging. The veterinarian is contacted if needed to verify health issues with the animals.

b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

Since all animals are procured from approved vendors, they are not quarantined upon receipt at the VA.

c. Describe the required/recommended stabilization period for each species.

All Laboratory Animals are given a 3-day acclimation period prior to being placed on/released to protocol.

3. Separation by Health Status and Species [*Guide*, pp. 111-112]

a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

Animals housed at the VMU are separated by species and health status. Since all rodents are procured from approved vendors and are housed in ventilated cages, animals from differing sources can be housed in the same room, depending on investigator preference and space availability.

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

None

c. Describe isolation procedures and related facilities for animals.

If the need arises to isolate an animal, these animals will be placed in a separate cage on a separate, isolated, ventilated rack, within the same room. If the need arises to isolate an animal, they are moved to a separate animal room for assessment, treatment or euthanasia.

C. Clinical Care and Management [*Guide*, pp. 112-115]

1. Surveillance, Diagnosis, Treatment and Control of Disease [*Guide*, pp. 112-113]

a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:

- the observers' training for this responsibility
- method(s) for reporting observations (written or verbal)
- method(s) for ensuring that reported cases are appropriately managed in a timely manner.

VMU Technicians observe all animals under their care, daily (including weekends and holidays). VMU Technicians have extensive on-the-job training and continuing education in detection of abnormal rodent behavior, signs of disease, pain and/or distress. Any animal welfare concerns are described on a morbidity card that is placed directly on the affected cage, and reported immediately to the VMU Supervisor. Technicians enter written abnormal findings in the Veterinary Checklist located in the VMU office along with a copy of the morbidity card. The Supervisor may contact the veterinarian by either telephone or e-mail depending on the severity of the condition. The veterinarian will provide assessment and treatment support, as needed, depending on the condition reported, i.e. he/she may immediately travel to the VMU, or will review the issue during twice a week Health Rounds. The veterinarian provides written documentation of the response to medical issues on the morbidity card and in the Veterinary Checklist document.

b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

A list of ill animals, i.e. the veterinary checklist, is maintained in the (b)(6) office along with copies of recent morbidity cards. The veterinarian reviews all sick animal cases during twice a week health rounds and annotates treatment and response on the morbidity card and in the veterinary checklist document. The Veterinarian, VMU Supervisor, or VMU Technicians may perform medical treatment as prescribed by the veterinarian (in consult with the PI). VMU personnel initiated treatments are noted on the Health Maintenance checklist in each animal room. The Animal Care Staff provides verbal and written communication to investigators when there is a welfare or protocol issue concerning research animals. The VMU Supervisor or veterinarian contacts the investigator and/or their staff by phone, text, or email. Staff may also leave notes or instructions directly on the cage of the affected animal.

c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

Disease prevention in the rodent colonies is primarily managed through procurement of animals with known health status from approved vendors, and periodic review of vendor-provided, barrier (animal) health reports.
This is augmented by the dirty bedding rodent sentinel program which is used for disease surveillance of Mouse Hepatitis Virus (MHV), Sendai virus, PVM, GDVII, MVM/MPV and Mycoplasma pulmonis. Ectromelia, Rat Coronavirus (RCV), KRV and PVM, Sialodacryoadenitis Virus (SDA), Sendai virus, Mycoplasma pulmonis, and Helicobacter sp.

2. Emergency Care [*Guide*, p. 114]

a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

On-call coverage for all animal welfare concerns is provided by the Veterinary Medical Consultants 24 hours a day, 365 days a year, per contract.

b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The Contract Veterinarian, or, his designee, has the authority to provide emergency treatment that is deemed necessary to all laboratory animals housed at the VMU. The Contract Veterinarian has full access to all animals and animal procedure areas in the VMU.

3. **Clinical Record Keeping** [*Guide*, p. 115]

a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

Individual medical records for rodents maintained at the VMU are not required by regulation or policy. The Veterinary Checklist of rodent medical cases is maintained by the VMU Supervisor in the (b)(6) (b)(6) which documents rodent care and treatment by the Veterinarian and VMU Staff. The Veterinarian, the IACUC, and the (b)(6) (b)(6) have access to these records. All Investigators and their Technicians are instructed to maintain records of laboratory animal use in protocol procedures. These records must document the use of anesthetics, analgesics, tranquilizers and euthanasia techniques, pre- and post-surgical care; and any information relevant to the animal's well-being. Investigator records of laboratory animal procedure are accessible to the IACUC members for review upon request.

b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

Contract Veterinarian, VMU Staff, Investigator, Protocol Personnel are all responsible for treatment of animals. Record of treatment is annotated/maintained in the Veterinary Checklist log that is kept in the VMU Administrative Office. All VMU Staff, the Veterinarian, the IACUC, and the investigator have access to these records.

c. Describe the role of the Attending Veterinarian in recordkeeping.

The Contract Veterinarian is responsible for twice weekly checks of the Veterinary Checklist log, making necessary annotations/adjustments to recommended treatments.

4. **Diagnostic Resources.** Describe available diagnostic methods used in the program including:

a. In-house diagnostic laboratory capabilities.

There are currently no in-house diagnostic laboratory capabilities at the VMU. The Diagnostic Laboratory in UTHSA, DLAR provides routine diagnostic services, quarterly screening tests on sentinel animals, and periodic blood work on postsurgical animals.

b. Commercially provided diagnostic laboratory services.

Quarterly sentinel specimens are submitted to (b)(6) (b)(6) for mouse and rat serology testing. This service is also provided through the UTHSA, DLAR Diagnostic Laboratory.

c. Necropsy facilities and histopathology capabilities.

There are no designated necropsy or histopathology facilities in the VMU. The Veterinary Pathologist at UTHSA, DLAR provides necropsy / histopathology services for VA investigators.

d. Radiology and other imaging capabilities.

The VMU has a Xenogen fluorescence imaging machine.

5. Drug Storage and Control

a. Describe the purchase and storage of controlled and non-controlled drugs.

All Controlled Drugs, used in research animals, are purchased through the VA Research Pharmacy. Controlled Substances are kept in the VMU Omnicell device in room (b)(6) Only the VMU Supervisor and his/her designee have access. The Omnicell is monitored, electronically, by VA Pharmacy personnel and inspected monthly by Controlled Substance Inspectors. Non-Controlled substances are kept in locked cabinets in room (b)(6)

b. Describe record keeping procedures for controlled substances.

Controlled Substance Records are maintained electronically by the Omnicell device and include date, time, principal investigator, responsible technician, amount issued, and purpose. Investigators are required to maintain records of administration on individual animal records. Investigators and technicians must show records substantiating administration before additional controlled drugs are issued.

D. Surgery [*Guide*, pp. 115-123]

1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

Investigators are required to consult with the Veterinarian on all aspects of animal surgery prior to submission of a protocol to the IACUC. The surgical plan is reviewed for feasibility of the animal model, surgical and anesthetic expertise required, personnel availability/training, surgical facility, equipment/supplies, pre-, intra- and post-op medications, and post-surgical care. After protocol approval and prior to scheduling surgery, the investigator must consult with the VMU Supervisor to coordinate all facets of the surgical procedure. All survival and non-survival surgeries are conducted within the VMU surgical suites.

2. Surgical Facilities [*Guide*, pp. 116-117, 144-145]

List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:

- the type of species (including rodents, fish, agricultural species, etc.)
- nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
- the amount of use [heavy (daily), moderate (weekly), or light]
- major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
- facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
- construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

Note: If preferred, the information requested in this section may be provided in Table.

Building: (b)(6) of the VA Hospital
Species: rats and mice
Room #(b)(6) light use
Nature of procedure: major/minor/emergency, survival/non-survival
Support equipment available:
Anesthesia apparatus w/ absorber and vaporizer unit = 3
Surgical lights = 8
Operating tables = 4
Infusion/withdrawal pump = 1

Suction apparatus = 2
Autoclave = 2
Ultrasonic cleaner = 1

3. **Surgical Procedures** [*Guide*, pp. 117-118]

   a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

Major survival surgery: Penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions.
Minor survival surgery: Does not expose a body cavity and causes little or no physiological impairment.
No special procedure classification is utilized at the VMU.

   b. How is non-survival surgery defined?

Non-survival surgery: An animal is euthanized before recovery from anesthesia.

4. Aseptic Technique [*Guide*, pp. 118-119]

   a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

Patient – hair clipped at surgery site, aseptic prep of surgery site i.e. initial scrub with dilute betadine then isopropyl alcohol in prep room, final scrub / prep in OR suite, sterile drapes, sterile instruments
Surgeon – dedicated scrubs, shoe covers, surgeon cap and mask, hand scrub, sterile gown, sterile gloves.

   b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

Steam is used to sterilize equipment, protective clothing, and drapes. Packs are double wrapped and taped with steam indicator autoclave tape and dated at time of sterilization. AMSCO Chemi-Strip (Steam) strips are inserted in all packs. Routine sterilization cycles run 30 minutes at 250 degrees F.

   c. Describe methods for instrument re-sterilization between serial surgeries.

Instrument re-sterilization between serial surgeries, if needed, is done using bead heat sterilizers with care taken to ensure that the instrument surfaces have cooled sufficiently before use to reduce risk of burns.

d. Indicate how effectiveness of sterilization is monitored.

The autoclave function is checked with a Verify (Steris) indicator monthly. Hi Vac autoclaves are checked monthly by D.A.R.T. (Steris) for air removal.

e. Describe surgical support functions provided by the program to investigators.

The VMU surgical suites provide the following surgical support functions: Gas anesthesia equipment, supplemental heat source, surgery table and surgery lights. Surgical assistance, anesthesia monitoring, autoclaving of instruments and surgical packs is also available to investigators.

5. **Intraoperative Monitoring** [*Guide*, p. 119]
Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

The principal surgical monitoring technique utilized during rodent surgery is evaluation of breathing rate and pattern. The "toe pinch" is utilized to determine that a surgical plane of anesthesia has been attained. A rectal temperature probe is also utilized to monitor body temperature. Information recorded for rodent anesthesia records is limited to procedure performed, anesthesia drugs and dose utilized, analgesics administered, recovery time and complications encountered (if any).

6. **Postoperative Care** [*Guide*, pp. 119-120]
Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

The investigator and his technicians are responsible for the post-operative care of all species which is described in the animal use protocol. Animals are generally moved to a warmed recovery cage and monitored continuously until making purposeful movements about the cage. Then they are returned to their home cage. Rodent anesthesia and surgery records are maintained by individual investigators and their technicians in a lab notebook.

E. Pain and Distress [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The potential for pain and distress during research procedures is assessed and categorized by the Investigator in the protocol document and verified during review by the IACUC using the current USDA pain categories.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

Citi training is mandatory for all VMU Staff and Protocol Personnel. Species-specific training is also required for research personnel. Additionally, training is provided to Protocol Personnel by Investigator and if needed by UTHSA DLAR.

F. Anesthesia and Analgesia [*Guide*, pp. 121-123]

1. List the agents used for each species.
Note: If preferred, this information may be provided in Table or additional Appendix.

Species: mouse, rat
Anesthetics: isoflurane; ketamine / xylazine; ketamine / xylazine / acepromazine
Analgesics: buprenorphine; acetaminophen; ibuprofen, per approved ACORP

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

The veterinarian discusses the use of anesthetics and analgesics with the investigator during the Veterinary Consult phase of protocol development. This is prior to submission of the animal protocol to the IACUC for review.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

Anesthesia effectiveness is monitored by the surgeon during surgery prep and the operative procedure. The principal surgical monitoring technique utilized during rodent surgery is evaluation of breathing rate and pattern. The negative "toe pinch" is utilized to determine that a surgical plane of anesthesia has been attained and is being maintained during the procedure. Analgesia effectiveness is principally monitored by the PI and his/her staff, post-operatively, and is based on knowledge of behavior that indicates rodents are experiencing pain, e.g. rough hair coat, guarding, aggression, etc. VMU Staff also monitor animals that have had surgery to determine if they are behaviorally normal or show behavioral signs of ineffective analgesia.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

Neuromuscular blocking agents are not used by VA researchers at the VMU.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

Gas anesthesia machines are required to have annual maintenance performed and documented to determine that they function properly. Vaporizers are sent for calibration, as needed, depending on results of the function testing.

G. Euthanasia [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
   - consideration of species, age, condition (e.g., gestational period, or neonatal) and
   - location(s) for the conduct of the procedure.

   Note: If preferred, this information may be provided in Table or additional Appendix.

All euthanasia methods are described in the protocol and approved by the IACUC. The principal methods of euthanasia utilized for rodents at the VMU are as follows:
- Carbon dioxide overdose via inhalation
- Overdose of pentobarbital based euthanasia solution
- Exsanguination/perfusion fixation in anesthetized animals
- Cervical dislocation in anesthetized animals

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

Euthanasia inhalation chambers are cleaned after each use; CO2 compressed gas cylinders are changed as needed.

3. Describe the methods used to confirm death of an animal.

Cervical dislocation on mice and heart cessation for rats is used to confirm death.

IV. Physical Plant [*Guide*, pp. 133-155]

A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

The STVHCS (b)(6) within the Research and Development Section. Access to the VMU is controlled via card-readers that are monitored by the VA Police. The VMU has (21) Animal Holding Rooms, (4) Procedure Rooms, and (2) dedicated Surgical Suites.

B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.

7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

1. There are 21 separate Animal Holding Rooms throughout the VMU, 4 Procedure Rooms, and 1 dedicated Surgical Suite. The VMU is a rectangle shaped facility, with rooms on each side of the hallway. Dirty cages are brought t(b)(6) for dumping. Once dumped, they are brought to the Tunnel Wash Room (b)(6) for processing. Clean cages are stored i(b)(6)

2. Animal Holding Rooms and Procedure Rooms are located along the same corridors.

3. All mice are housed in Allentown MicroVENT caging, with all rats housed in Animal Care Systems M.I.C.E. racks.

4. Animal room floors are constructed of a poured, seamless epoxy resin in good condition. Some support rooms and corridors are covered with vinyl tile and are in good condition.

Walls, including cage wash, are constructed of sealed lath and plaster. Some of these areas are further protected by floor to ceiling fiberglass panels. Some walls, in low impact areas, are sealed drywall. Any exterior windows in an animal room are covered with black acrylic and sealed.

Ceilings are lath and plaster with sealed acoustical tiles and are in good condition.

Animal room doors are sealed solid wood, 84" high, 36-44 inches wide with sealed viewing ports and plastic kickboard/wainscot.

5. The HVAC system of the VMU is maintained/operated through the Energy Management System located in the Energy Systems Control Center in the basement of the hospital. Air conditioning systems are inspected on a quarterly basis. Ventilation rates are inspected on a yearly basis. All air into the animal rooms is 100% fresh air and all air is exhausted 100% to the outside. The system is monitored 24/7.

6. Access to all Animal Holding Rooms, Procedure Rooms, and Surgical Suites is controlled using the Edstrom Watchdog System. Access is granted on an individual basis with access to rooms being limited to only required rooms.

7. Any windows, within Animal Holding Areas, have been blacked out. Temperature and humidity, of all rooms, is monitored via the Edstrom Watchdog System and on a daily basis by VMU Staff during Daily Health Checks.

8. Flammable agents are stored in the VMU Storage Room, (b)(6) Any corrosive agents are stored i(b)(6) Disinfectants, detergents, and other like items are stored in(b)(6)

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

N/A

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

N/A

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. **Power** [*Guide*, p. 141]

For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:

- Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
- History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

All Allentown Micro-Isolators are connected to Emergency Power outlets. In the event of a primary power failure, the secondary power source is provided by VA generator. In the event both systems fail, the tertiary power source is provided by the emergency generator, which insures minimal hallway light and power to designated receptacles throughout the VMU.
Other than scheduled power outages, the VMU has experienced no power failures.

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

N/A

E. Other Facilities [*Guide*, pp. 144, 150]

1. **Other Animal Use Facilities** [*Guide*, pp. 146-150]
Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

N/A

2. **Other Animal Program Support Facilities**
Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

UTHSA, DLAR provides Veterinary Support, diagnostic laboratory procedures, sentinel program, and animal transport.

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution's animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at: accredit@aaalac.org

Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

Abbreviation/Acronym	Definition
VA	Veterans Affairs
STVHCS	South Texas Veterans Health Care System
ALMD	Audie L. Murphy Division
VMU	Veterinary Medical Unit
UTHSA	Univ. of Texas Health, San Antonio
IO	Institutional Official
VMC	Veterinary Medical Consultant
IACUC	Institutional Animal Care and Use Committee
A,COS	Associate, Chief of Staff
SOW	Statement of Work
SRS	Subcommittee for Research Safety
IBC	Institutional Biosafety Committee
BSLT	Biological Science Laboratory Technician
MOU	Memorandum of Understanding
CITI	Collaborative Institutional Training Initiative
PPE	Personal Protective Equipment
ACORP	Animal Component of Research Protocol
ASIST System	Automated Safety Incident Surveillance Tracking System
P.A.P.R.	Powered Air Purifying Respirator
SOP	Standard Operating Procedure
DLAR	Department of Laboratory Animal Resources
FCR	Full Committee Review
DMR	Designated Member Review
PI	Primary Investigator
RCO	Research Compliance Officer
HVAC	Heating, Ventilating, Air Conditioning
M.I.C.E.	Microenvironmental comfort, Isolation, Containment, Enrichment
IVC	Individually Ventilated Cage
ATP Swabs	Adenosine Triphosphate Swabs
D.A.R.T.	Daily Air Removal Test

Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, satellite housing facilities, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). Detailed information for satellite housing facilities is requested in Appendix 17. Include only one line entry for satellite housing facilities in this table to provide the total square footage for all satellite housing areas listed in appendix 17. If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

Animal Housing and Support Sites						
Location (building, site, farm name, etc.[a])	**Distance from main facility[b]**	**Approx. ft², m², or acreage for animal housing**	**Approx. ft², m², or acreage for support or procedures**	**Species housed**	**Approx. Daily Animal Census by species**	**Person in charge of site**
STVHCS, ALMD	(b)(6)				4,100/ 100	(b)(6)
Satellite Housing Facilities Total (Expand in Table 17)						

Totals:	7,700ft²	2,000ft²	
	7,700ft2		

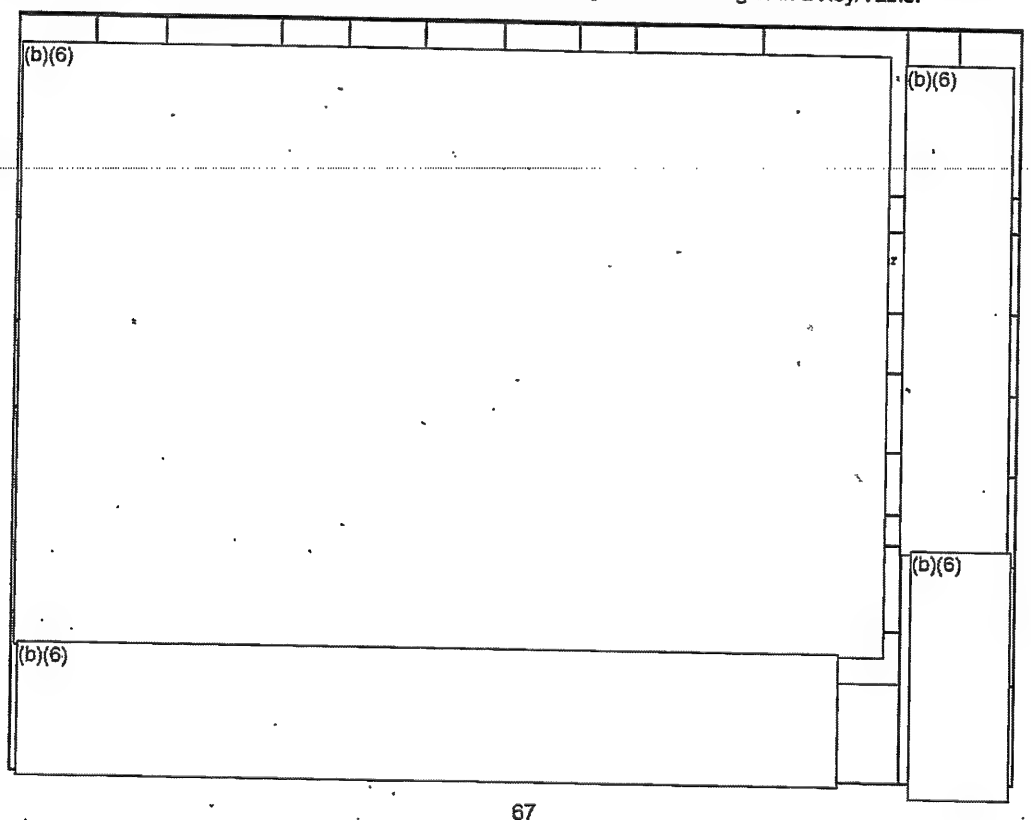
Appendix 2: Summary of Animal Housing and Support Sites

Total animal housing and support space:	**(please specify ft^2 or m^2)**	

[a]Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.
[b]Campus or site map(s) may also be provided in lieu of this information.

Appendix 3: Line Drawings

Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5" x 11" or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.

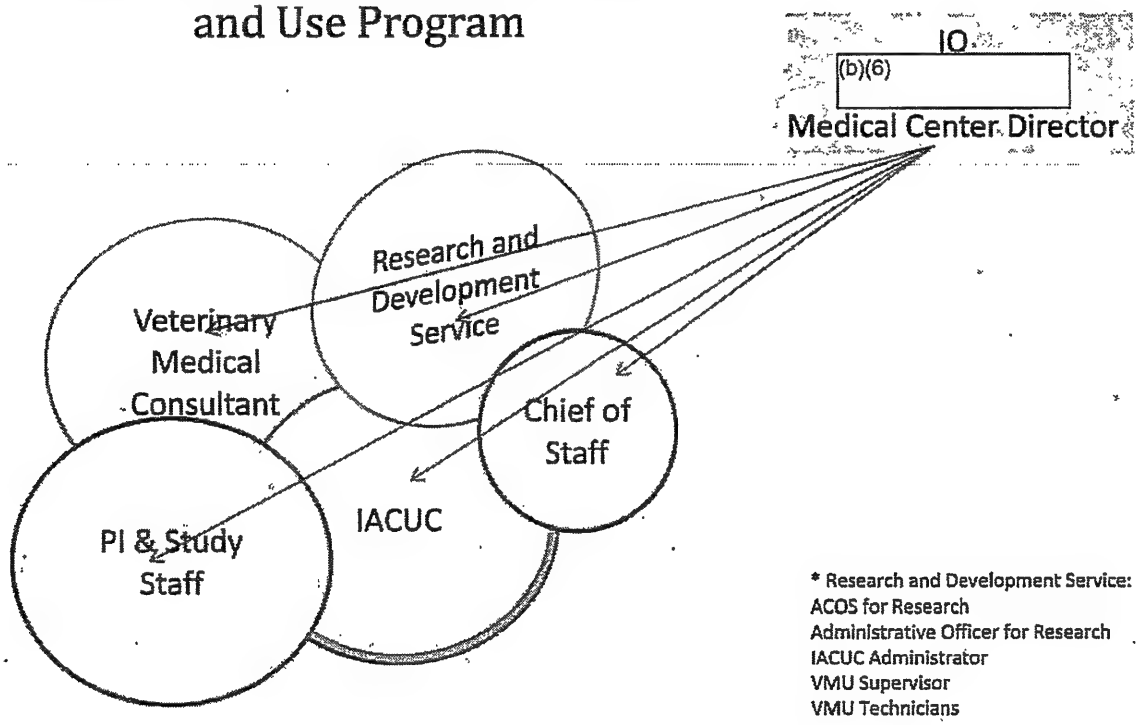


Appendix 4: Organizational Chart(s)

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.

See attached

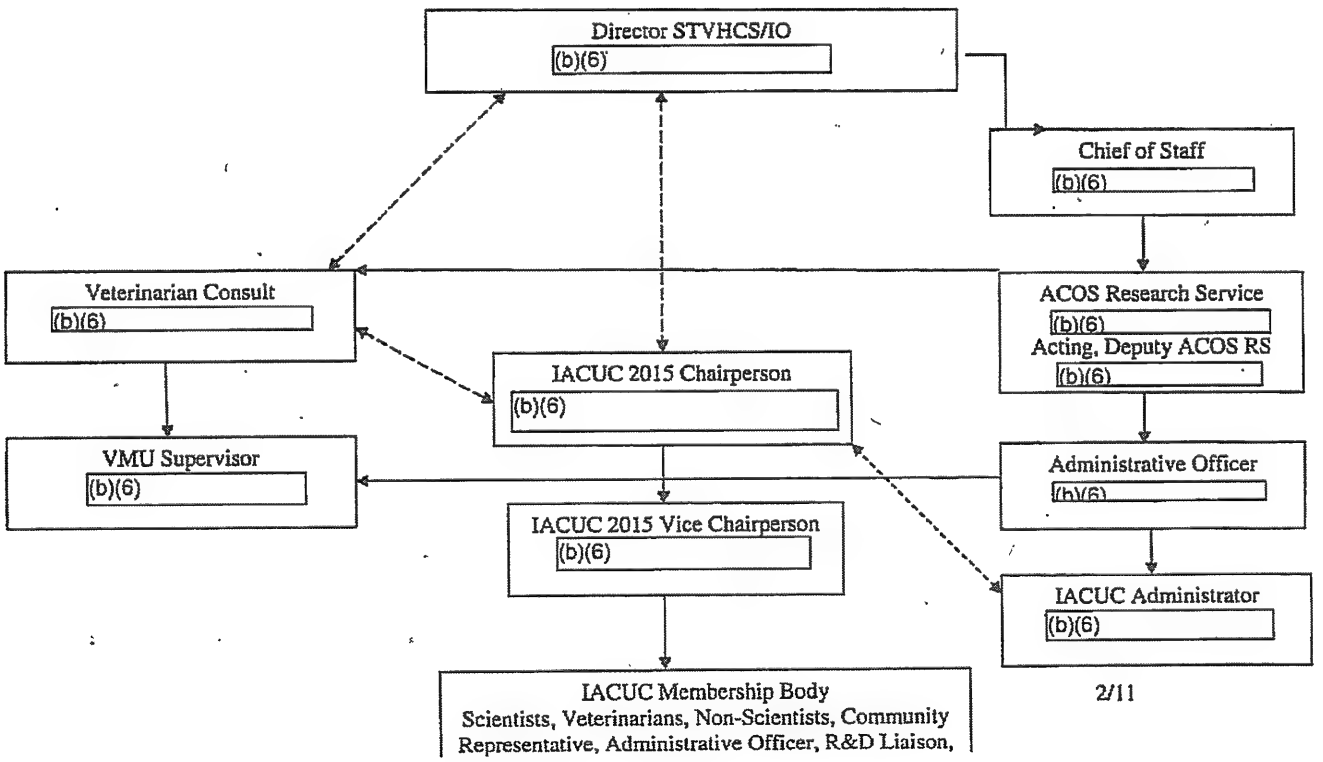
STVHCS Organizational Structure for the Institutional Animal Care and Use Program



* Research and Development Service:
ACOS for Research
Administrative Officer for Research
IACUC Administrator
VMU Supervisor
VMU Technicians

Appendix 4

IACUC Organization Chart



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Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)			Mouse	988	C/E					X	
			Mouse	160	D	X				X	
			Mouse	300	D	X					
(b)(6)			Mouse	240	D	X				X	
			Mouse	1325	B/C/D					X	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)											
			Rats	528	D	X	X				
			Dog	34	D	X					
			Rabbit	70	D	X					
(b)(6)			Rat	1080	E						
			Rat	1056	C/E	X				X	
				70							B/16

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)			Mouse	1450	B/C/D	X				X	
			Mouse	200	C						
			Mouse	800	C					X	
			Mouse	704	B/D						
			Mouse	358	B/C						
			Mouse	294	C						
(b)(6)			Rat	122	C						
			Mouse	1620	B/C/D	X				X	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)			Mouse	2405	B/C/E						
			Rat	1148	B/C/E						
			Mouse	1763	B/C/E						
			Rat	388	C/D	X					
(b)(6)			Mouse	1140	C/D	X					
			Mouse	3348	B/C/D					X	
			Mouse	168	B/C					X	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)											
			Rat	3238	B/C/D						
			Mouse	440	A						
			Mouse	1654	B/C					X	
			Mouse	854	B/D					X	
			Mouse	64	D						
(b)(6)			Mouse	380	C/D						
			Mouse	934	B/C/D/E					X	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)			Rat	1816	C/D/E	X				X	
			Mouse	2180	B/C/D/E					X	
			Mouse	4664	B/C/D	X	X			X	
(b)(6)			Mouse	7426	D					X	
			Mouse	736	C/D					X	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)				1004	C/D					X	
				960	D					X	
				870	B/D	X				X	
				690	B/D						
(b)(6).				150	D						
				2062	B/D/E	X				X	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)			Mouse	72	E					X	
			Mouse	2041	E					X	
			Mouse	220	E					X	
			Mouse	250	C						
			Mouse	480	B/C						
(b)(6)			Mouse	5196	B/C/D	X	X			X	
			Mouse	4730	B/C/D	X	X			X	

Appendix 5: Animal Usage

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(6)			Mouse	9085	B/C/E	X					
			Mouse	1524	B/C/D					X	
			Rat	483	C/D	X				X	
			Mouse	6084	B/C/D	X				X	

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.
(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)
(5) Prolonged Restraint (PR)
(6) Hazardous Agent Use (HAU)
(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

Appendix 5: Animal Usage

In the Table below, provide an approximate annual usage for all species:

Animal Type or Species	Approximate Annual Use	Animal Type or Species	Approximate Annual Use
Mice	4,100		
Rat	100		

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 6: Personnel Medical Evaluation Form

Provide a ***blank*** copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).

See attached

SUPERVISOR/PI CERTIFICATION

By signature, I certify that I have provided _____ with information regarding STVHCS Research Service Animal Care and Use Program, Occupational Health and Safety for Research Personnel with Significant Animal Contact operating instruction and the availability of Learning Management System Occupational Health training, course 32755. I have provided necessary training and a printed copy of the above program guide.

Printed Supervisor/PI Name:

Signature: _____

Date:

OCCUPATIONAL PHYSICIAN

By signature, I verify that I reviewed and discussed, with the participant, the submitted Occupational Health Questionnaire and potential risks associated with the involvement in animal-related research. The participant was offered medical services appropriate to the risks.

Printed Occupational Health Physician Name:

Signature: _____

Date:

Periodic Animal Exposure Questionnaire

Name: _____ Social Security Number (Last 4): _____

Job Title: _____ Extension: _____

Bldg./Room #: _____

1. I no longer work with animals (including animal tissues, waste, body fluids, carcasses, or animal quarters) at the VA Medical Center. Yes No (if Yes, skip to #4).

2. Show any **change** in animal contact within the VA Medical Center in the past year. Write a plus (+) for continuing contact; (++) for new animal contact; (-) for animals no longer working with.

Form 1 - Animal Exposure Listing

Animal Exposure Listing	
_____Dogs	_____Swine
_____Cats	_____Sheep
_____Rabbits	_____Rodents
_____Guinea Pigs	_____NHPs
_____Mice	_____Other
_____Goats	_____Gerbils
_____Hamsters	_____Rats

3. Check total amount of contact time with animals in the past year (include contact with animal tissues, waste, body fluids, carcasses, or animal quarters):

_____ More than one hour per week

_____ One hour or less per week

_____ Other (explain): _____

4. List any additions or deletions of human or animal pathogens or infectious diseases you have worked with in the past year:

Additions: _____

Deletions: _____

5. List the date of your last Tuberculosis (TB) screening: (Tuberculin Skin Test or TB Symptoms Checklist):

_____

6. List date of Hepatitis B, Tetanus, or Rabies immunizations received this past year:

   Hepatitis B: _____ Tetanus: _____ Rabies: _____

7. Circle any condition(s) below that you have developed over the past year:

   Hay Fever Asthma Sinusitis Other Chronic Respiratory Infection

   Allergic Skin Problems Eczema

Comments: _____

_____

8. Check symptoms you developed this past year and how often you have them:

Form 2 - Symptom Occurrence Checklist

Symptoms	Never	Monthly	Weekly	Daily
Watery, Itchy Eyes				
Runny, Stuffy Nose				
Sneezing Spells				
Frequent, Dry Cough				
Wheezing In Chest				
Rash or Hives				
Shortness of Breath				
Trouble Swallowing				

9. Do animals cause the above symptoms? If so, please list the animals.

_____

Appendix 7: IACUC/OB Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

See attached

IACUC Membership Roster
Last Updated: July 23, 2018

Name	Job Title	Membership	From	To
(b)(6)	(b)(6)	R&D Liaison	4/2018	4/2021
		Local Ex-Officio (A)	8/2016	8/2019
		Local Ex-Officio (P)	06/2017	06/2020
		Chair	11/2017	10/2018
		Scientist	6/2015	5/2018
		At Large Scientist	11/2015	10/2018
		Veterinarian (P)	7/2010	Indefinite
		Veterinarian (A)	6/2014	Indefinite
		Industrial Hygienist	6/2018	5/2021
		Non-Scientist (A)	7/2017	6/2020
		Local Ex-Officio	5/2016	Indefinite
		Local Ex-Officio	05/2017	05/2020
	(b)(6)	Non-Scientist (P)	8/2018	7/2021
		Scientist	12/2017	11/2020
(b)(6)		Local Ex-Officio	5/2018	4/2021
		Scientist	9/2016	9/2018
		Non-Affiliated (P)	7/2017	6/2020
		Scientist	11/2015	10/2018
		Vice-Chair	11/2017	10/2018

P = Primary voting; A= Alternate voting in absence of primary. Local Ex-Officio is non-voting.

Appendix 8: IACUC/OB Minutes

Please provide the latest two Minutes of the IACUC/OB meetings.

See attached

South Texas Veterans Health Care System
7400 Merton Minter Blvd
San Antonio, Texas 78229

Institutional Animal Care and Use Committee (IACUC)

MINUTES October 10, 2018 1:00-2:00 Location: Research Conference Room, (b)(6)

CHAIR (E)	(b)(6)
FACILITATOR	
RECORDER	
ATTENDEES	
P	
P	
P	
P	
P	
P	
E	
P	
E	
P	
E	
E	
P	
P	
E	
P	
P	(b)(6)
Guest	

Quorum Present: yes, voting minimum 5; total voting present 5

Administrative Comments [Information to be shared with all Committee Members]

- **CONFLICT OF INTEREST DISCLOSURE** – a conflict of interest is any financial arrangement, situation or action that affects or is perceived to exert inappropriate influence on the design, review, conduct, results or reporting of research activities or findings. When a member has a conflict of interest, the member should notify the IACUC Chair and may not participate in the IACUC review or approval except to provide information. Members who have a conflict of interest may not be counted toward a quorum and may not vote.

- **CITI Essentials of the IACUC, biennial training compliance:**

NAME	*EXPIRATION*
(b)(6)	June 28,2020
	November 6, 2020
	September 13, 2020
	June 25, 2020
	March 8, 2019
	July 9, 2021
	July 7, 2021
	January 11, 2019
	July 9, 2020
	June 8, 2021
	In Progress
	September 2, 2019
	February 7, 2021
	March 8, 2019
	February 7, 2021
	February 6, 2021

- **Adverse Event Reporting:** none

Approval of Minutes **IACUC Administrator**

DISCUSSION	(b)(6) called the meeting to order at 1:00 pm. The IACUC Meeting Minutes of September 12, 2018 were reviewed for accuracy and completeness.

CONCLUSIONS	**A motion was made and seconded to approve the minutes as written.** _5_ Approved _0_ Disapproved (Tabled) _0_ Abstain _0_ Require Modifications to secure approval (RMSA) ___ RMSA "substantive issues" followed by convened Full Committee review (FCR) after revision ___ RMSA "non-substantive" followed by Designated Member (DMR) – requires 2 reviewers' concurrence before chair and vet's signature; FCR—not required ___ RMSA "minor administrative" approved by committee but must have administrative review before chair and vet's signature

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Forward minutes to the R&D Committee review	IACUCA	9/17/18

(Closed)

New Business –

DISCUSSION	(b)(6)

CONCLUSION	**A motion was made and seconded to approve ACORP, pending non-substantive recommendations.** ___ Approved _5 _Disapproved (Tabled) _0_ Abstain ___ Require Modifications to secure approval (RMSA) ___ RMSA "substantive issues" followed by convened Full Committee review (FCR) after revision ___ RMSA "non-substantive" followed by Designated Member (DMR) – requires 2 reviewers' concurrence before chair and vet's signature; FCR—not required __ RMSA "minor administrative" approved by committee but must have administrative review before chair and vet's signature

ACTION ITEMS		PERSON RESPONSIBLE	DEADLINE
(b)(6)	Return to November IACUC	IACUCA	10/29/18

(Open)

DISCUSSION	(b)(6)

CONCLUSION	**A motion was made and seconded to approve ACORP, pending non-substantive recommendations.** _5_ Approved ___ _Disapproved (Tabled) _0_ Abstain _5_ Require Modifications to secure approval (RMSA) ___ RMSA "substantive issues" followed by convened Full Committee review (FCR) after revision _5_ RMSA "non-substantive" followed by Designated Member (DMR) – requires 2 reviewers' concurrence before chair and vet's signature; FCR—not required __ RMSA "minor administrative" approved by committee but must have administrative review before chair and vet's signature

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Review animal numbers with (b)(6) return to IACUC	IACUCA	10/29/18

(Open)

DISCUSSION	**Modification:** (b)(6)

CONCLUSION	**A motion was made and seconded to approve ACORP, pending non-substantive recommendations.** ___ Approved __5_Disapproved (Tabled) _0_ Abstain ___ Require Modifications to secure approval (RMSA) ___ RMSA "substantive issues" followed by convened Full Committee review (FCR) after revision ___ RMSA "non-substantive" followed by Designated Member (DMR) – requires 2 reviewers' concurrence before chair and vet's signature; FCR—not required __ RMSA "minor administrative" approved by committee but must have administrative review before chair and vet's signature

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Review animal numbers with (b)(6) provide necessary Appendices; return to IACUC	IACUCA	10/29/18

(Open)

DISCUSSION	**Modification:** (b)(6) (b)(6)

CONCLUSION	**A motion was made and seconded to approve ACORP, pending non-substantive recommendations.** ___ Approved __5_Disapproved (Tabled) _0_ Abstain ___ Require Modifications to secure approval (RMSA) ___ RMSA "substantive issues" followed by convened Full Committee review (FCR) after revision ___ RMSA "non-substantive" followed by Designated Member (DMR) – requires 2 reviewers' concurrence before chair and vet's signature; FCR—not required __ RMSA "minor administrative" approved by committee but must have administrative review before chair and vet's signature

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Review animal numbers with (b)(6) return to IACUC	IACUCA	10/29/18

(Open)

REVIEW OF REQUESTS FOR CONTINUED APPROVAL OF ANIMAL USE/ANNUAL
NOTE: Continuing reviews were available on with Agenda thumbnails and in the IACUCA's office (b)(6) for review prior to designated meeting. The continuing reviews were also displayed at the meeting and discussed.

DISCUSSION	(b)(6)
CONCLUSION	**A motion was made and seconded to approve Continuing Reviews NTE the VA IACUC expiration date.** _5_ Approved ___ Disapproved (Tabled) _0_ Abstain

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Forward to R&D Committee	IACUCA	10/16/18

(closed)

Meeting Adjournment

CONCLUSION	A motion was made and seconded to adjourn the meeting.

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Next scheduled meeting is November 14, 2018 in the Research Conference Room. Send reminder and agenda to committee members.	IACUCA	9/17/18

(b)(6)

These minutes were Approved/Disapproved at a convened meeting on 11/14/18

(b)(6)

South Texas Veterans Health Care System
7400 Merton Minter Blvd
San Antonio, Texas 78229

Institutional Animal Care and Use Committee (IACUC)

MINUTES September 12, 2018 1:00-2:00 Location: Research Conference Room, (b)(6)

CHAIR (E)	(b)(6)
FACILITATOR	
RECORDER	(b)(6)
ATTENDEES	
P	
P	
E	
P	
E	
P	
E	
P	
E	
P	
E	
E	
P	
E	
E	(b)(6)
E	
E	
Guest	

Quorum Present: yes, voting minimum 5; total voting present 5

Administrative Comments [Information to be shared with all Committee Members]

- **CONFLICT OF INTEREST DISCLOSURE** – a conflict of interest is any financial arrangement, situation or action that affects or is perceived to exert inappropriate influence on the design, review, conduct, results or reporting of research activities or findings. When a member has a conflict of interest, the member should notify the IACUC Chair and may not participate in the IACUC review or approval except to provide information. Members who have a conflict of interest may not be counted toward a quorum and may not vote.

- **CITI Essentials of the IACUC, biennial training compliance:**

NAME	*EXPIRATION*
(b)(6)	

- **Adverse Event Reporting:** none

Approval of Minutes **IACUC Administrator**

DISCUSSION	(b)(6) called the meeting to order at 1:00 pm. The IACUC Meeting Minutes of August 11, 2018 were reviewed for accuracy and completeness.

CONCLUSIONS	**A motion was made and seconded to approve the minutes as written.** _5_ Approved _0_ Disapproved (Tabled) _0_ Abstain _0_ Require Modifications to secure approval (RMSA) ___ RMSA "substantive issues" followed by convened Full Committee review (FCR) after revision ___ RMSA "non-substantive" followed by Designated Member (DMR) – requires 2 reviewers' concurrence before chair and vet's signature; FCR—not required ___ RMSA "minor administrative" approved by committee but must have administrative review before chair and vet's signature

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Forward minutes to the R&D Committee review	IACUCA	9/17/18

(Closed)

New Business –

DISCUSSION	(b)(6) [redacted]
CONCLUSION	**A motion was made and seconded to approve ACORP, pending non-substantive recommendations.** _5_ Approved ___Disapproved (Tabled) _0_ Abstain ___ Require Modifications to secure approval (RMSA) ___ RMSA "substantive issues" followed by convened Full Committee review (FCR) after revision ___ RMSA "non-substantive" followed by Designated Member (DMR) – requires 2 reviewers' concurrence before chair and vet's signature; FCR—not required ___ RMSA "minor administrative" approved by committee but must have administrative review before chair and vet's signature

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Forward to R&D Committee	[redacted]	9/17/18

(Closed)

REVIEW OF REQUESTS FOR CONTINUED APPROVAL OF ANIMAL USE/ANNUAL
NOTE: Continuing reviews were available on with Agenda thumbnails and in the IACUCA's office (b)(6) for review prior to designated meeting. The continuing reviews were also displayed at the meeting and discussed.

DISCUSSION	(b)(6) (b)(6) (b)(6)
CONCLUSION	**A motion was made and seconded to approve Continuing Reviews NTE the VA IACUC expiration date.** _5_ Approved ___ Disapproved (Tabled) _0_ Abstain

ACTION ITEMS	PERSON RESPONSIBLE	DEADLINE
Forward to R&D Committee	[redacted]	9/17/18

(closed)

Meeting Adjournment

CONCLUSION	A motion was made and seconded to adjourn the meeting.	
ACTION ITEMS	**PERSON RESPONSIBLE**	**DEADLINE**
Next scheduled meeting is October 10, 2018 in the Research Conference Room. Send reminder and agenda to committee members.	IACUCA	9/17/18

(b)(6)

These minutes were Approved/Disapproved at a convened meeting on 10/10/18

(b)(6)

Appendix 9: IACUC/OB Protocol Form

Please attach a ***blank*** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.

See attached

ACORP Complete (with appendices)

Last Name of PI▶
Protocol No. Assigned by the IACUC▶
Official Date of Approval▶

ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)
Main Body
VERSION 4

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

A. **ACORP Status.**

1. Full Name of Principal Investigator(s)▶

2. VA Station Name (City) and 3-Digit Station Number▶

3. Protocol Title▶

4. Animal Species covered by this ACORP▶

5. Funding Source(s). Check each source that applies:

▶( ) Department of Veterans Affairs.
▶( ) US Public Health Service (e.g. NIH).
▶( ) Private or Charitable Foundation -- Identify the Foundation:
▶( ) University Intramural Funds – Identify the University and Funding Component:
▶( ) Private Company – Identify the Company:
▶( ) Other – Identify Other Source(s):

6. Related Documentation for IACUC reference.

a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:

(1) Title of project▶

(2) If approved by the R&D Committee, give the date of approval▶

b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:

(1) Identify the studies described in the previously approved ACORP that have already been completed
▶

(2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
▶

(3) Describe any study results that have prompted changes to the protocol, and briefly summarize those changes, to guide the reviewers to the details documented in other Items below.
▶

c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).

(1) Title of other protocol ▶
(2) IACUC approval number of other protocol ▶
Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ▶

7. Indicate the type(s) of animal use covered by this protocol (check all that apply):

▶( ) Research
▶( ) Teaching or Training
▶( ) Testing
▶( ) Breeding and colony management only; not for any specific research project
▶( ) Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
▶( ) Other. Please specify▶

Proposal Overview

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.
▶

C. **Experimental Design.**

1. **Lay Summary.** Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.
▶

2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.

a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.
▶

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is strongly encouraged; see ACORP instructions.
▶

c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

D. **Species.** Justify the choice of species for this protocol.
▶

Personnel

E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name▶
Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that the PI will perform personally	Experience with each procedure in the species described in this ACORP

2. Other research personnel (copy the lines below for each individual)

Name▶
Animal research experience ▶

Qualifications to perform specific procedures

Specific procedure(s) that this individual will perform	Experience with each procedure in the species described in this ACORP

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name▶

Qualifications to perform specific support procedures in the animals on this protocol

Specific support procedure(s) assigned to this individual	Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training)

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

Name of Individual	Working with the VA IACUC	ORD web-based species specific course (Identify the species)	Any other training required locally (Identify the training)

F. **Training to be provided.** List here each procedure in Item E for which anyone is shown as "to be trained", and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter "N/A"
▶

G. **Occupational Health and Safety.**

1. Complete one line in the table below for each of the personnel identified in Item E:

Name	Enrollment in OHSP		Declined optional services	Current on Interactions with OHSP? (yes/no)
	VA program	Equivalent Alternate Program – identify the program		
	( )	( )	( )	
	( )	( )	( )	
	( )	( )	( )	

2. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

▶ ( ) Yes. Describe them ▶

▶ ( ) No.

Animals Requested

H. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study (see ACORP Instructions, for guidance, including specific terminology recommended for the "Health Status" column):

Description (include the species and any other special features not shown elsewhere in this table)	Gender	Age/Size on Receipt	Source (e.g., Name of Vendor, Collaborator, or PI of local breeding colony)	Health Status

I. **Numbers of animals requested.** See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

USDA Category B

Procedures▶						
Species / Experimental Group / Procedures(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category B TOTAL**

USDA Category C

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category C TOTAL**

USDA Category D

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category D TOTAL**

USDA Category E

Procedures▶						
Species / Experimental Group / Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**Category E TOTAL**

TOTALS over all Categories

Species / Experimental Group /Procedure(s)	Year 1	Year 2	Year 3	Year 4	Year 5	**GRAND TOTAL**

J. **Management of USDA Category D procedures.** Indicate which statement below applies, and provide the information requested.

▶ ( ) This protocol does NOT include any Category D procedures.

▶ ( ) This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

Procedure	Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery)	Person(s) responsible for the monitoring	Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered)

K. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.

▶ ( ) This protocol does NOT include any Category E procedures

▶ ( ) This protocol INCLUDES Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.
▶

Veterinary Care and Husbandry

L. **Veterinary Support.**

1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

   Name▶
   Institutional affiliation▶
   email contact▶

2. Veterinary consultation during the planning of this protocol.

   Name of the laboratory animal veterinarian consulted▶
   Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ▶

M. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

a. Species	b. Type of housing*	c. Number of individuals per housing unit**	d. Is this housing consistent with the *Guide* and USDA regulations? (yes/no***)	e. Estimated maximum number of housing units needed at any one time

*See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:
▶

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)
▶

***Use Appendix 9 to document "departures" from the standards in the *Guide*.

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

a. Species	b. Description of Enrichment*	c. Frequency

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.
▶

3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

▶ ( ) This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.
▶

▶ ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.
▶

▶ ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.
▶

▶ ( ) This ACORP does NOT include use of any animals that will require customized routine husbandry.

N. **Housing Sites.** Document in the tables below each location where animals on this protocol may be housed.

▶ ( ) Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

Building	Room number	Inside of VMU?	
		Yes	No
		( )	( )
		( )	( )
		( )	( )

▶ ( ) Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table.

Name of Non-VA Facility	Is this facility accredited by AAALAC?		Building	Room Number
	Yes -- enter status*	No**		
	( )	( )**		
	( )	( )**		
	( )	( )**		

*See ACORP Instructions, for a list of AAALAC accreditation status options.

**For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

Special Features

O. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

▶ ( ) Some or all of the animals on this protocol WILL be used in the production and harvesting of antibodies. Check "Appendix 2" in Item Y, below, and complete and attach Appendix 2, "Antibody Production".

▶ ( ) NO animals on this protocol will be used in the production and harvesting of antibodies.

P. **Biosafety.** Will any substances (other than those used in routine husbandry or veterinary care) be administered to the animals on this protocol?

▶ ( ) This protocol INVOLVES administration of substances to the animals other than those used in routine husbandry and veterinary care. Check "Appendix 3" in Item Y, below, and complete and attach Appendix 3, "Biosafety".

▶ ( ) This protocol does NOT involve administration of any substances to the animals other than those used in routine husbandry and veterinary care.

Q. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for each of the procedures to be performed on animals on this protocol.

Procedure	Surgical?		Bldg/Room Number	Requires transport through non-research areas?	
	Yes	No		Yes – describe method of discreet transport	No
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )
	( )	( )		( )	( )

R. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

Body Fluid, Tissue, or Device to be Collected	Collected AFTER Euthanasia	Collected BEFORE Euthanasia		
		Blood Collection Associated with Antibody Production (Appendix 2, "Antibody Production")	Collected as Part of a Surgical Procedure (Appendix 5, "Surgery")	Other Collection from Live Animals (Appendix 4, "Antemortem Specimen Collection")
	( )	( )	( )	( )
	( )	( )	( )	( )
	( )	( )	( )	( )

S. **Surgery.** Does this protocol include any surgical procedure(s)?

▶ ( ) Surgery WILL BE PERFORMED on some or all animals on this protocol. Check "Appendix 5" in Item Y, below, and complete and attach Appendix 5, "Surgery".

▶ ( ) NO animals on this protocol will undergo surgery.

T. **Endpoint criteria.** Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these criteria. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

U. **Termination or removal from the protocol.** Complete each of the following that applies:

▶ ( ) Some or all animals will NOT be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

▶ ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

Check each method that may be used on this protocol	Method of Euthanasia	Species	AVMA Classification		
			Acceptable	Conditionally Acceptable	Unacceptable
( )	CO_2 from a compressed gas tank Duration of exposure after apparent clinical death▶ Method for verifying death▶ Secondary physical method▶		( )	( )	( )
( )	Anesthetic overdose Agent▶ Dose▶ Route of administration▶		( )	( )	( )
( )	Decapitation under anesthesia Agent▶ Dose▶ Route of administration▶		( )	( )	( )

( )	Exsanguination under anesthesia Agent▶ Dose▶ Route of administration▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )
( )	Other (Describe) ▶		( )	( )	( )

1. For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe how the conditions for acceptability will be met:
   ▶

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:
   ▶

3. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.
   ▶

4. Instructions for the animal care staff in case an animal is found dead.
   a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ▶

   b. Describe how the PI's staff should be contacted.
      ▶ ( ) Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)
      Name▶
      Contact Information▶

      ▶ ( ) There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
      ▶

V. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented. See ACORP Instructions, for examples.

Name of Procedure	Identify Where the Details of the Procedure are Documented		
	SOP (title or ID number)*	Other Items in this ACORP -- specify the Item letter(s)	Appendix 6
		Items:	( )**
		Items:	( )**
		Items:	( )**
		Items:	( )**

*If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

**If any special procedure is detailed in Appendix 6, check "Appendix 6" in Item Y, below, and complete and attach Appendix 6.

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

W. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work.

1. Document the database searches conducted.
   List each of the potentially painful or distressing procedures included in this protocol.
   ▶

   Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

Name of the database	Date of search	Period of years	Potentially painful or	Key words and/or search strategy used	Indicate which mandate each search addressed

		covered by the search	distressing procedures addressed		Replacement of animals (item W.2)	Reduction in numbers of animals used (item W.3)	Refinement to minimize pain or distress (item W.4)	Lack of unnecessary duplication (item W.5)
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )
					( )	( )	( )	( )

2. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.
▶

3. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.
▶

4. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.
▶

5. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.
▶

X. Other Regulatory Considerations.

1. Controlled drugs.

a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

Controlled substances	Storage		Personnel Authorized to Access	Location for Use		Procurement	
	Double-locked	Not Double-locked*		VA Property	Not on VA Property	VA Pharmacy	Non-VA
	( )	( )*		( )	( )	( )	( )
	( )	( )*		( )	( )	( )	( )

	( )	( )*		( )	( )	( )	( )

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.
▶

b. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:

▶ ( ) Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.

▶ ( ) Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.

▶ ( ) Other. Explain▶

2. **Human patient care equipment or procedural areas.** Does this protocol involve use of any human patient care equipment or procedural areas?

▶ ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".

▶ ( ) No human patient care equipment or procedural areas will be used for the animal studies on this protocol.

3. **Explosive agents.** Does this protocol involve use of any explosive agent?

▶ ( ) Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".

▶ ( ) No explosive agent(s) will be used as part of this protocol.

Y. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

Appendices. Indicate which of the Appendices are required and have been completed and attached to this protocol. Do not check off or attach any appendices that are not applicable to this ACORP.

▶ ( ) Appendix 1, "Additional Local Information"
▶ ( ) Appendix 2, "Antibody Production"
▶ ( ) Appendix 3, "Biosafety"
▶ ( ) Appendix 4, "Ante-mortem Specimen Collection"
▶ ( ) Appendix 5, "Surgery"
▶ ( ) Appendix 6, "Special Husbandry and Procedures"
▶ ( ) Appendix 7, "Use of Patient Care Equipment or Areas for Animal Studies"
▶ ( ) Appendix 8, "Use of Explosive Agent(s) within the VMU or in Animals"

▶ ( ) Appendix 9, "Departures from "Must" and "Should" Standards in the *Guide*"

Standard Operating Procedures (SOPs). List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

Item	SOP		Approval Date
	Title	ID	
C.2.c			
M.1			
M.2			
U.4.a			
U.4.b			
V			

Z. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

   a. **Certification by Principal Investigator(s):**

   I certify that, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

   I understand that further IACUC approval must be secured before any of the following may be implemented:

   - Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
   - Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should be assigned, or that might otherwise be considered a significant change from the approved protocol;
   - Performing any additional procedures not already described in this ACORP;
   - Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my after-hours contact information to the animal care staff for use in case of emergency.

Name(s) of Principal Investigator(s)	Signature	Date

b. **Certification by IACUC Officials.**

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:

▶ ( ) No minority opinions were submitted by any IACUC participant for inclusion.

▶ ( ) Minority opinions submitted by IACUC participants are copied here ▶

▶ ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled "IACUC Minority Opinion" (indicate the number of pages▶)

Name of Attending Veterinarian (VMO or VMC)	Signature	Date
(b)(6)		
Name of IACUC Chair	Signature	Date
(b)(6)		

2. **Appendix 2. Antibody Production.** No signatures required.

3. **Appendix 3. Biosafety.**

   a. **Certification by PI(s) and IACUC Officials:**

   We certify that:

   - Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;

   - All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

Name(s) of Principal Investigator(s)	Signature(s)	Date
Name of Institutional Veterinarian	Signature	Date
(b)(6)		
Name of IACUC Chair	Signature	Date
(b)(6)		

   b. **Certification by Biosafety Official.** I certify that:

   - Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "toxic", "infectious", "biological", or "contains recombinant nucleic acid";

   - The use of each of the agents thus identified as "toxic", "infectious", or "biological", or "contains recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;

   - The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee	Signature	Date

c. **Certification by Radiation Safety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "radioactive";
- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee	Signature	Date

4. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.

5. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:
  - Identification of each animal such that care for individual animals can be documented.
  - Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
  - Documentation of the administration of all medications and treatments given to the animals;

including those given to reduce pain or stress.
- Daily records covering at least the period defined as "post-operative" by local policy.
- The signature or initials of the person making each entry.

Name(s) of Principal Investigator(s)	Signature(s)	Date

6. **Appendix 6. Special Husbandry and Procedures.** No signatures required.

7. **Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.**

a. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

Name(s) of Principal Investigator(s)	Signature(s)	Date

b. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
(b)(6)		
Name of the Manager of the Human Patient Care Equipment	Signature	Date

c. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

Name of IACUC Chair	Signature	Date
(b)(6)		
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
(b)(6)		
Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment	Signature	Date
Name of ACOS for R&D	Signature	Date
(b)(6)		
Name of Chief of Staff	Signature	Date
Name of Director or CEO of the Facility (Hospital or Clinic)	Signature	Date

8. **Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

   a. **Certification by the Principal Investigator(s).**

   I certify that, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

   I further certify that:

   - Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
   - All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
   - Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;

- Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

Name(s) of Principal Investigator(s)	Signature(s)	Date

b. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

Name of IACUC Chair	Signature	Date
(b)(6)		
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
(b)(6)		
Name of Safety/Biosafety Officer for the Facility	Signature	Date
Name of ACOS for R&D	Signature	Date
(b)(6)		
Name of VISN Regional Safety Officer	Signature	Date

9. **Departures from "Must" and "Should" Standards in the *Guide*.** No signatures required.

ACORP Complete (with appendices)

Last Name of PI▶
Protocol No. Assigned by the IACUC▶
Official Date of Approval▶

ACORP Appendix 1
ADDITIONAL LOCAL INFORMATION
VERSION 4

(This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

ACORP APPENDIX 2
ANTIBODY PRODUCTION
VERSION 4

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.

   a. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

Immunization day (e.g. day -7, 0, 7, 30, etc.)	Antigen		Adjuvant – give name, concentration, and volume (ml)	Total injection volume (ml) per animal (antigen plus adjuvant)	Divided among how many injection sites?	Injection route and location of injection site(s) on body
	Name	Total amount (mg) and volume (ml)				

   b. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.
   ▶

   c. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur:
   ▶

   d. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.
   ▶

2. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

▶ ( ) No, the production and harvest of antibodies on this protocol does not involve survival collection of blood.

▶ ( ) Yes, this protocol requires the collection of blood in a survival procedure, before (as a "pre-bleed") and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

a. Describe each survival collection of blood in the table below, including any "pre-bleeds" prior to immunizations:

Site of Blood Collection	Amount of Blood Collected at any one time, expressed as volume (ml) and as % of body weight (assume 1 ml = 1 gram)	Number of Blood Collections	Time Interval(s) Between Successive Collections	Volume Replace-ment? (yes/no)

b. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

▶ ( ) No anesthetics, tranquilizers, or analgesics will be administered for blood collection. Explain why it is appropriate or necessary NOT to administer pain-relieving agents:
▶

▶ ( ) Yes. Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):
▶

c. Will volume replacement be provided for blood that is collected?

▶ ( ) Volume will NOT be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.
▶

▶ ( ) Volume WILL be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).
▶

3. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

▶ ( ) No, this protocol does NOT involve terminal blood collection for harvest of antibodies.
▶ ( ) Yes, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

a. Describe the method(s) to be used for euthanasia and exsanguination:
▶

b. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

▶ ( ) No anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s). Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

▶

▶ ( ) Yes. Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

▶

c. Describe how you will make sure that the animals are dead after collection of the blood:
▶

4. **Harvesting Feeder Cells.** Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.
▶

5. **Expansion of Hybridoma Cell Line(s) *in vivo*.** Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

▶ ( ) No animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.

▶ ( ) Yes, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

a. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.
▶

b. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

Hybridoma cell line designation	Number of animals to be used for ascites production	Priming agent and volume	Number and timing of priming injections	Volume of injected hybridoma cells	Number of abdominal taps before euthanasia

c. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol
▶

d. List the criteria for euthanasia of animals prior to the last planned abdominal tap.
▶

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

ACORP APPENDIX 3
BIOSAFETY
VERSION 4

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of <u>All</u> Materials Administered to Animals on this Protocol.** Complete the table below for <u>all</u> materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

Material (Identify the specific agent, device, strain, construct, isotope, etc.)	**Source** (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors)	**Nature of Material**						
		Toxic Agent (Item 4)	Infectious Agent (Item 5) -- Enter the CDC Biosafety Level (BSL 1, 2, 3, or 4)	Biological Agent (Item 6)	Radioactive Agent (Item 7)	Contains Recombinant Nucleic Acid (Item 8)	Routine Pre- or Post-Procedural Drug	Euthanasia agent
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )
		( )	( )BSL_	( )	( )	( )	( )	( )

2. **Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

Material* (Identify the specific agent, device, strain, construct, isotope, etc.)	**Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi) and **Volume** (ml)	**Diluent* or Vehicle***	**Route** of admin	**Frequency or duration** of admin	**Reason** for Administration and **Expected Effects**	Location of **Further Details** in this ACORP (specify " Main Body" or " App #" , and identify the Item)	Administration Under **Anesthesia, sedation, or tranquilization** (Y/N)

*Each material, diluent, or vehicle that is listed as FDA approved or is labeled "USP" is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm) or animals (http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847). Designate with a * each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)
▶

3. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:

   a. For each material with "Y" entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):
   ▶

   b. For each material with "N" entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.
   ▶

4. **Toxic Agents.** Complete the table below for each of the materials listed as a "toxic agent" in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

Name of Toxic Agent	a. Mutagen	b. Carcinogen	c. Teratogen	d. Select Agent?			e. Other – specify toxic properties
				Not a Select Agent	Select Agent Used in Sub-threshold Quantities	Select Agent that Requires Registration/Approval	
	(_)	(_)	(_)	(_)	(_)	(_)*	(_)▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶
	( )	( )	( )	( )	( )	( )*	( )▶

*For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶
Registration Number ▶
Registration Date ▶
Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶
Date of approval▶

5. **Infectious Agents.** Complete the table below for each of the materials listed as an "infectious agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name and BSL	a. ABSL	b. Drug Sensitivity Panel Available? (Describe)	c. Select Agent?

Number of Infectious Agent	Number *		Not a Select Agent	Select Agent used in Sub-threshold quantities	Select Agent that Requires Registration/Approval
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**
		(Yes/No)	( )	( )	( )**

*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

Name of agent ▶
Justification for applying ABSL measures that are less protective than those recommended ▶

**For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶
Registration Number ▶
Registration Date ▶
Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO ▶
Date of approval ▶

6. **Biological Agents.** Complete the table below for each of the materials listed as a "biological agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Biological Agent	Screening for Infectious Agents

7. **Radioactive Agents.** Complete the table below for each of the agents listed as a "radioactive agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Radioactive Agent (specify the isotope)	Authorized Individual	Approving Committee or Official

8. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as "contains recombinant nucleic acid", indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

Name of Agent that Contains Recombinant Nucleic Acid	Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*	Exempt
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )

9. **Potential for Pain or Distress.** Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

Name of Agent	Nature of Potential Pain/Distress	Measures to Alleviate Pain/Distress

10. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as "toxic", "infectious", "biological", "radioactive", or "contains recombinant nucleic acid" (detailed in Items 4 – 8). This item specifically addresses members

of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.

a. Complete the table below.

Name of Hazardous Agent	Approving Committee or Official	Institution (VA or affiliate)	Names of Animal Facility Staff Members at Risk

b. Detail how the individuals listed in the table above (Item 10.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.
▶

11. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.

ACORP Appendix 4
ANTEMORTEM SPECIMEN COLLECTION
VERSION 4

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

Specimen Collected	Site and Method of Collection	Anesthesia (Yes/No)	Amount Collected Each Time	Volume Replacement (Yes/No/NA)	Total Number of Collections per Animal	Time Intervals Between Successive Collections

2. **Use of Anesthetics, Tranquilizers, or Analgesics.**

   a. For each specimen described in Item 1, above, as being collected WITHOUT anesthesia, complete Items 2.a(1) and 2.a(2), below:

      (1) Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).
      ▶

      (2) Completely describe any method of physical restraint that may be used.
      ▶

   b. For each specimen described in Item 1, above, as being collected WITH anesthesia, complete the following table:

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) and volume (ml)	Route of administration	Frequency of administration

3. **Volume Replacement for Fluid Collections.**

   a. For each fluid specimen described in Item 1, above, for which NO volume replacement will be provided, explain why not.
   ▶

b. For each fluid specimen described in Item 1, above, for which volume replacement WILL be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).
▶

4. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).
▶

ACORP Appendix 5
SURGERY
VERSION 4

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

Surgery		Terminal	Survival		
#	Description (specify the species, if ACORP covers more than one)		Minor	Major	One of Multiple*
1		( )	( )	( )	( )*
2		( )	( )	( )	( )*
3		( )	( )	( )	( )*
4		( )	( )	( )	( )*

*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

a. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:
▶

b. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):
▶

2. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below.)

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

3. **Personnel.** Complete the table below for each individual who will be involved in any of the surgeries on this protocol.

Name	Surgery	Role in Surgery

	#(s) (see Item 1)	Surgeon	Assistant	Manage Anesthesia	Other (describe)
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )

4. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

Building	Room Number	Surgery #(s) (see Item 1)	Type of Space		
			Dedicated Surgical Facility	Other Dedicated Surgical Space	Other Space not Dedicated to Surgery
			( )	( )*	( )*
			( )	(*)	( )*
			( )	( )*	( )*
			( )	( )*	( )*

*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery on this protocol
▶

5. **Pre-operative protocol.**

a. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

Surgery #(s) (see Item 1)	Fast (Specify Duration)	Withhold Water (Specify Duration)	Place Intravenous Catheter(s) (Specify Site(s))	Other – Describe
1	( ) --	( ) --	( ) --	( ) --
2	( ) --	( ) --	( ) --	( ) --
3	( ) --	( ) --	( ) --	( ) --
4	( ) --	( ) --	( ) --	( ) --

b. **Pre-operative medications.** Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal.

Agent	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of administration (e.g., times/day)	Pre-operative period of treatment (e.g., immediate, or # of days)

c. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

6. **Intra-operative management.**

a. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery.

Agent	Paralytic*	Surgery #(s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of dosing
	( )*				
	( )*				
	( )*				

* For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.
▶

b. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.).
▶

c. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery.
▶

7. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.

a. Complete the table below for each survival surgery listed in Item 1, above.

Surgery # (see Item 1)	Survival Period	Measures for Maintaining Sterility							
		Sterile Instruments	Surgical Cap	Sterile Gloves	Surgical Scrub	Sterile Drapes	Sterile Gown	Face Mask	Other*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*

* Describe any "other" measures to be taken to maintain sterility during surgery.
▶

b. For each surgery, describe the immediate post-operative support to be provided to the animals.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

c. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

Surgery # (see Item 1)	Agent*	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of Dosing (e.g., times/day)	Period of treatment (e.g. days)
1					
2					
3					
4					

*For each surgery for which NO post-operative analgesic will be provided, enter "none" in the "Agent" column, and explain here why this is justified:
▶

d. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care.

Surgery # (see Item 1)	Medication	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of dosing (e.g. times/day)	Period of treatment (e.g. days)

e. Post-operative monitoring. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

(1) Immediate post-operative monitoring

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

(2) Post-operative monitoring after the immediate post-operative period

Surgery # (see Item 1)	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

f. Post-operative consequences and complications.

(1) For each surgery, describe any common or expected post-operative consequences or

complications that may arise and what will be done to address them.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(2) List the criteria for euthanasia related specifically to post-operative complications:

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(3) In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanatized instead.)
▶

g. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

Surgery # (see Item 1)	Location of Records	Name(s) of Individual(s) Responsible for Maintaining Written Records	Research Personnel	Veterinary Staff
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

8. **Certification.** The PI must sign the certification statement in Item Z.5 of the main body of the ACORP.

ACORP APPENDIX 6
SPECIAL HUSBANDRY AND PROCEDURES
VERSION 4

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in a SOP or in another item or Appendix of the ACORP. For each special procedure, check all features that apply.

Special Procedure		Features							
Number	Brief Description	Husbandry	Restraint	Noxious Stimuli	Exercise	Behavioral Conditioning	Irradiation	Imaging	Other**
1		( )	( )	( )	( )	( )	( )	( )	( )
2		( )	( )	( )	( )	( )	( )	( )	( )
3		( )	( )	( )	( )	( )	( )	( )	( )
4		( )	( )	( )	( )	( )	( )	( )	( )

*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

**Describe any "Other" features that are involved.
▶

a. Provide a complete description of each special procedure listed above, including the duration of the procedure, how frequently it will be repeated in any one animal, and any effects it is expected to have on the animal:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. Explain why each of these special procedures is necessary:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

2. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

Procedure Number (see Item 1)	Responsible Individual(s)	
	Carrying Out Procedure	Monitoring the Animals
1		
2		
3		
4		

3. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and, if so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

Procedure Number (see Item 1)	Expected Potential Pain and/or Distress			
	No	Yes		
		Description	To Be Relieved	Not to Be Relieved
1	( )		( )[a]	( )[b]
2	( )		( )[a]	( )[b]
3	( )		( )[a]	( )[b]
4	( )		( )[a]	( )[b]

a. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

Procedure Number (see Item 1)	Agent	Dose (mg/kg) & vol (ml)	Route of admin	Freq of admin (times/day)	Duration of admin (days post-procedure)
1					
2					
3					
4					

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. For each procedure for which potential pain and/or distress is expected and will NOT be prevented or alleviated, provide the scientific justification for this:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

4. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

Procedure Number (see Item 1)	Monitoring Methods	Endpoint Criteria
1		
2		

3		
4		

ACORP APPENDIX 7
USE OF PATIENT CARE EQUIPMENT AND/OR AREAS
FOR ANIMAL STUDIES
Version 4

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s)** ▶

2. **Equipment to be Used.**

   a. Identify the equipment ▶

   b. Procedure(s) to be performed with this equipment ▶

   c. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients.
   ▶

3. **Human Patient Care Procedural Areas to be Used.**

   a. Location(s) ▶

   b. Animal species to be studied or treated ▶

   c. Number of individual animals to be studied or treated ▶

   d. Date(s) ▶

   e. Time(s) of day ▶

   f. Procedure(s) to be performed on the animals in these areas ▶

   g. Protection and cleaning of patient care room surfaces ▶

   h. Benefits to VA patients. Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients.
   ▶

   i. Necessity for use of human patient care areas. Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.
   ▶

   j. Animal transport. Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas.
   ▶

k. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.
▶

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP.

ACORP APPENDIX 8
USE OF EXPLOSIVE AGENT(S) WITHIN THE (b)( ) OR IN ANIMALS
VERSION 4

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s)** ▶

2. **Explosive agents to be used.**

   a. Identify the explosive agents. Complete the table below.

Agent Number	Name(s) Used to Refer to the Agent in This ACORP	Name Shown for this Agent on the MSDS on File	CAS number	Location of the MSDS on File
1				
2				
3				
4				

   b. Locations where the explosive agents will be used. Complete the table below.

Agent Number	Location Where Agent Will Be Used			
	Building	Room Number	Within the (b)( )	Outside of (b)( )
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

   c. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).
   ▶

   d. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. See ACORP App. 8 Instructions, for a list of commonly used precautions.
   ▶

   e. Period of use.
   Beginning no earlier than (date) ▶
   Ending no later than (date) ▶

   f. Animals that will be administered explosive agents:

Species ▶
Approximate weights of individual animals ▶
Approximate number of animals ▶

3. **Personnel.** Complete the table below for each individual who will handle any of the explosive agents as part of this protocol.

Name of Individual	Explosive Agent(s) to be Handled	Training and Experience Pertinent to Handling Explosive Agents

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.8) of the main body of this ACORP.

ACORP Appendix 9
DEPARTURES FROM "MUST" AND "SHOULD" STANDARDS IN THE *GUIDE (2011)*
VERSION 4

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.

For each IACUC-approved "departure" of this protocol from a "Must" or "Should" standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.):

Copy the lines below for each departure.

Briefly summarize the "Must" or "Should" standard, and provide the number(s) of the page(s) on which it appears in the *Guide*
▶

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.
▶

Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure
▶

SIGNIFICANT CHANGE TO APPROVED ANIMAL PROTOCOL

This is an Excel spreadsheet. Enter information in shaded areas only.

1. Principal Investigator Information

Date: 9/12/16 Protocol #: _____ Species: _____
Principal Investigator(s) _____
Service _____ Mailstop _____
Phone _____ Pager _____ email _____
Co-investigator(s) _____

Title of Protocol:

2. Is there an addition of title or change to title? Yes ☐ No ☐

New Title:

3. In the space provided, please give the rationale for the changes you propose. (A brief synopsis of what you are doing and why, and how it relates to your research goals.) If there is a lengthy explanation, please include a summary sentence here, and full explanation on an attached sheet.

Please complete any appropriate sections of this form where changes will be made from the approved protcol. Mark "N/A" in the sections left the same as in the approved protocol.

4. Animal Subject Description

Species: _____ Strain: _____ Weight and/or Age: _____
Number of Animals Req: _____ Sex: _____

USDA Category B List by year the number of animals that will be bred or purchased for breeding, but is not used for experiments. This includes breeders, young that cannot be used because of improper genotype or gender, and any other animals that will not have any research procedures performed on them or participate in research studies. If numbers cannot be determined exactly, estimate as closely as possible. (Note: If tail snips are necessary for genotyping, this category is not appropriate).

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category C List, by year, the number of animals that will undergo procedures that involve no or only very brief pain or distress, with no need for or use of pain relieving drugs. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, and the collection of cells and/or tissues from animals after euthanasia has been performed.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category D List by year the number of animals that will undergo procedures involving potential pain or distress that is relieved by appropriate anesthetics, sedatives, or analgesics. Examples include major and minor surgery performed under anesthesia (survival or non-survival), tissue or organ collections prior to euthanasia, painful procedures performed under anesthesia(such as retro-orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, and experiments involving infectious or other hazardous materials in animals that have provisions for immediate euthanasia if they become sick or effectively prevent pain and/or suffering. If an endpoint is used that involves significant pain or distress, consideration should be given to putting animals into Category E.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

USDA Category E List by year, the number of animals that will undergo procedures in which pain or stress is NOT relieved with the use of anesthetics, analgesics, tranquilizers, or by euthanasia. Examples include studies in which animals are allowed to die without intervention (e.g. LD_{50}, mortality as an end-point), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, and noxious stimulation.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

TOTALS: Bring totals for each year down, by breed/strain/mutant.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

5. Is there is a change in personnel? Yes ☐ No ☐
   If yes, please fill out the "Personnel Change" form (see tab at bottom).

6. Are there changes in the test substances being used? Yes ☐ No ☐
   If yes, Appendix 3, Test Substances, must be submitted

   Has approval for the use of hazardous material (radioisotopes, infectious agents, carcinogens, etc.) been obtained from the proper authority? _____

   Please list approval number(s) and approval date(s): _____
   If you have not yet received an approval number simply state "pending". _____

7. Does this protocol involve new or changed invasive procedures to collect tissues or body fluids from live animals? Yes ☐ No ☐
   If yes, Appendix 4, Antemortem Specimen Collection, must be submitted
   Note: Blood collection for Antibody Production is covered in Appendix 2, Antibody Production

8. Does this protocol involve new surgical procedures or is more than one major surgical procedure to be performed on a single animal? Yes ☐ No ☐
   If yes, Appendix 5, Surgery, must be submitted

9. Will animals be subject to new procedures involving prolonged restraint, food or water deprivation or noxious stimuli, are there any changes in behavioral testing or husbandry, housing or diet? Yes ☐ No ☐
   If yes, Appendix 6, Special Husbandry & Procedures, must be submitted.

10. Are there any changes in method of Euthanasia or in the disposal of animals? Yes ☐ No ☐
    If this procedure does not meet the recommendations of the 2000 AVMA Panel on Euthanasia, provide justification. Please consult with the Veterinary Medical Officer if you have any questions on acceptable methods.

http://www.avma.org/resources/euthanasia.pdf)

11. Has a literature search been performed, or other method used to assure that proposed work is not unnecessarily duplicative, and that alternative or less painful procedures cannot be used? Yes ☐ No ☐

Name of the database(s)	Date performed	Period (years) covered by each search	Key words and/or search strategy used	Indicate below for which mandate each search was conducted by placing an "X" in the proper column.			
				Alternative computer models or in vitro techniques (Item W.2)	Alternative use of less-sentinent species (Item W.3)	Alternative use of less stressful model or methods, or fewer animals (item W.4)	Lack of un-necessary duplication (Item W.5)

12. Is there any additional information that would help the IACUC evaluate your proposed change to protocol? Yes ☐ No ☐

I affirm that to the best of my knowledge, information provided in this description is complete and accurate, that this research is not an unnecessary duplication of previous research, and that no changes will be made without the advance approval of the Subcommittee on Animal Studies. All personnel listed on this protocol will be provided a signed copy of this protocol and any subsequent protocol updates.

Principal Investigator _____ Date _____

[redacted] Date _____

Date _____

South Texas Veterans Health Care System — October, 2011
Research & Development Program

CHANGES TO PERSONNEL FOR APPROVED ANIMAL USE STATEMENTS

Use a separate form for each person to be added/removed

This is an Excel spreadsheet. Enter information in shaded areas only.

1. **Principal Investigator Information**

Date: _____
Principal Investigator(s) _____
Phone _____ Mailstop/Box#: _____ Email _____

2. **Personnel Information**

Name of person: _____ Employer: _____
List role of above listed person on your project(s), i.e. Co-Investigator, Lead Tech, etc: _____

This person is to be:

☐ **Removed** (answer yes or no below and skip to section 6 for signature)

Will another person be taking over his/her role on the project?
☐ No ☐ Yes If yes, name of person: _____

☐ **Added** (continue on to answer sections 3, 4, 5 and 6)

3. Is this person enrolled in the Occupational Health Program? _____
In the space below, summarize the procedures this person will be performing on these protocols:

4. List protocol numbers, titles, and associated species (if adding to more than 3 protocols, list on separate sheet).
Number: _____ Title: _____ Species: _____
Number: _____ Title: _____ Species: _____
Number: _____ Title: _____ Species: _____

5. **Personnel Training and Qualification Information**

Completion date for online training course "Working with the VA IACUC": _____

Animal Use Training Dates and Location (VA or UW) for each species listed above (within last five years):
Species: _____ Date: _____ Location: _____
Species: _____ Date: _____ Location: _____
Species: _____ Date: _____ Location: _____

In the box below, include email address and relevant training information, such as degree, years and type of prior experience working with laboratory animals, and any other pertinent animal use experience:

6. I affirm that to the best of my knowledge, information provided in this request is complete and accurate, and that no changes to personnel will be made without the advance approval of the IACUC. All personnel listed on this protocol will be provided a signed copy of this protocol and any subsequent protocol updates.

_____ _____
Principal Investigator Date

RETURN THIS COMPLETED FORM TO IACUC SECRETARY, MAILSTOP 151 (BOX: 358280)

IACUC OFFICE USE ONLY

Training verified by Secretary on: _____ Initials: _____

[redacted] _____ Date

_____ Date

South Texas Veterans Health Care System — October, 2011
Research & Development Program

MINOR/NON-SIGNIFICANT CHANGE TO ANIMAL USE PROTOCOL

This is an Excel spreadsheet. Enter information in shaded areas only.

1. Principal Investigator Information

Date: _____ Protocol #: _____ Species: _____
Principal Investigator(s) _____
Service _____ Mailstop _____
Phone _____ Pager _____ email _____
Co-investigator(s) _____

Title of Protocol: _____

3. In the space provided, please give the rationale for the changes you propose. (A brief synopsis of what you are doing and why, and how it relates to your research goals.) If there is a lengthy explanation, please include a summary sentence here, and full explanation on an attached sheet.

I affirm that to the best of my knowledge, information provided in this description is complete and accurate, that this research is not an unnecessary duplication of previous research, and that no changes will be made without the advance approval of the Subcommittee on Animal Studies.
All personnel listed on this protocol will be provided a signed copy of this protocol and any subsequent protocol updates.

_____ _____
Principal Investigator Date

This change involves: IACUC OFFICE USE ONLY
☐ Animal Care ☐ Administrative Change ☐ Other: _____

_____ Date

_____ Date

CONTINUING REVIEW FOR NON-HUMAN RESEARCH PROTOCOLS

Project Title:

VA Project No: Date Protocol Initiated:

Principle Investigator:

R&D Approval Date: R&D Renewal Date:

Is this a final report – (all data have been collected and analyzed)? ☐ **YES (Complete pages 3 & 4 only)** ☐ **NO (Complete all applicable pages) -- List principal investigator, co-investigators, and research associates. Fill-in blanks to the right of names.**

NAME and DEGREE	ROLE (i.e. PI, Co-Inv, Research Associate)	TYPE OF VA APPOINTMENT & SERVICE (i.e. VA, WOC, Contract, IPAA)	Phone	Email	Research Conducted off-site (yes r no)	VA funded Study (yes or no)	Involved in lab work (yes or no)	Financial conflict of interest exists for this project (yes or no)	R&D Eligibility (FOR OFFICE USE ONLY)

(Note: Non-WOC personnel must check-in as a visitor with the Research Service when on VA property if they do not have a current VA affiliation).

CHECK APPROPRIATE BOX (ONLY CHECK ONE) AND SIGN BELOW

☐ I have reviewed the current and approved Research Animal Scope of Work for all applicable personnel and verify that it includes all required duties and procedures for conducting this protocol. NOTE: If changes to a Research Animal Scope of Work are needed to cover the required duties and procedures for conducting this protocol, a new Research Animal Scope of Work must be submitted and approved prior to adding these personnel to the protocol.

Options (for Office Use Only):
- Lab (*in vitro*)
- Animal (*in vivo*
- No privileges

CONTINUING REVIEW FOR NON-HUMAN RESEARCH PROTOCOLS

Project Title:

VA Project No: Date Protocol Initiated:

Principle Investigator:

R&D Approval Date: R&D Renewal Date:

	☐ No personnel listed above are subject to the Research Scope of Practice policy (all personnel listed are only involved in non-human research). I certify that all personnel listed have completed CITI Working with the IACUC, specific species, and Biosecurity training. In additional all personnel have been cleared by VA or UTHSCSA Occupational Health Clinics and that the certification has been presented to the IACUC administrator. **PI Signature** **Date**	
	For R&D Office Use Only Stipulation Deadline for R&D Review: Reviewed and Verified by R&D Office Staff: Date:	

*Study personnel who are not physically conducting research on VA property or not directly working with research subjects

Refer to the Research Service website (b)(6) for all required forms to establish research privileges. **NOTE: New personnel may not work on protocols until research privileges have been approved by the R&D Office.

2. Conflict of Interest:
Have there been changes in the financial arrangements or other non-financial arrangements for investigators or research personnel on this project that would require update of the Conflict of Interest Disclosures?

☐ **YES –** (updated Conflict of Interest Disclosures are attached http://www.southtexas.va.gov/Research/Documents/LFI.pdf)
☐ **NO –** (update of Conflict of Interest Disclosures are not required)

3. Is this an IRB approved EXEMPT protocol or has it been determined to be nonhuman research?
☐ **NO –** (Documents submitted to the UTHSCSA IRB for Continuing Review will be obtained from the IRB for review by the R&D Committee. No duplicate IRB documents need to be submitted.)

CONTINUING REVIEW FOR NON-HUMAN RESEARCH PROTOCOLS

Project Title:

VA Project No: Date Protocol Initiated:

Principle Investigator:

R&D Approval Date: R&D Renewal Date:

☐ **YES** – Provide a descriptive update/ summary of progress made on this project. If the project has been completed during the last year, summarize what the project accomplished overall. The description should include any changes to study objectives, research plan, methods, findings, or clinical relevance. This update/summary will be presented to the R&D Committee as part of the Annual Review of the project.

7. **Project Abstract Update:**

Principal Investigator Signature (REQUIRED): _____ **Date:** _____
For R&D Office Use Only

Reviewed and Verified by R&D Office Staff:
Date:

APPROVAL **DISAPPROVAL**

R&D Committee Chairman Signature _____
Date:

Research Safety Review

Please review your currently approved "Research Protocol Safety Survey" and respond to the following questions:

a. Are any new or modified experimental procedures involving the use of biological, chemical, physical, or radiation hazards anticipated in the re-approval period that are **not contained in the currently approved** "Research Protocol Safety Survey"?

☐ **NO**
☐ **YES** (attach a revised "Research Protocol Safety Survey" http://www.southtexas.va.gov/Research/Forms_STVHCS_Research.asp)
NOTE: The Research Safety Committee and the R&D Committee must approve changes prior to implementation.

CONTINUING REVIEW FOR NON-HUMAN RESEARCH PROTOCOLS

Project Title:

VA Project No: Date Protocol Initiated:

Principle Investigator:

R&D Approval Date: R&D Renewal Date:

b. Have all research personnel reviewed the current "Research Protocol Safety Survey"?

☐ NO
☐ YES

c. Does this research project have Radiation Safety approval?
☐ N/A
☐ NO
☐ YES (provide current Radiation Safety expiration date _____)
For questions related to Radiation Safety approval contact (b)(6)

For Office Use Only

Reviewed and Verified by R&D Office Staff:
Date:

APPROVAL **DISAPPROVAL**

Safety Subcommittee Chairman Signature _____
Date:

Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.

See attached

▶ Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
▶ Station Number: 671
▶ City, State: San Antonio, Texas
▶ Date of Semiannual Evaluation: June 28, 2018

VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section A. Review of the Program

The Review of the Program is largely an administrative evaluation of all of the policies, plans, standard procedures, and systems under which the institution fulfills its responsibilities to ensure humane animal care and use. Some of the programmatic items may appear similar to items included in Section B (Inspection of the Facilities), but the focus here (Review of the Program) is on what is intended or expected, while Section B focuses on observed implementation.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted.

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee".
"1200.07" refers to the "VHA Handbook 1200.07, Use of Animals in Research".
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
   (Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]* be completed every 6 months. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "▶" symbols indicate required information:

▶ Date(s) of the most recent previous Review of the Program: December 16, 2017
▶ Date(s) on which this Review of the Program was conducted: June 28, 2018

▶ Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
▶ Station Number: 671
▶ City, State: San Antonio, Texas
▶ Date of Semiannual Evaluation: June 28, 2018

Names of voting IACUC members who participated in the Program Review:
(The Program Review team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b)(6)	(b)(6)	6/28/18
(b)(6)		6/28/18

Non-IACUC members who participated in the Program Review:

Name	Title	Date(s) of Participation

3) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (Approved by the IACUC)
Minor Deficiency
Significant Deficiency

4) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section A), provide details in Part 2 of this form.

5) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡ denotes a new "must" item
† denotes a new "should" item

▶ Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
▶ Station Number: 671
▶ City, State: San Antonio, Texas
▶ Date of Semiannual Evaluation: June 28, 2018

I. Institutional Policies and Responsibilities

A. Shared Responsibilities						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
100†	A formal written MOU, contract, or agreement is in place for any arrangement in which the VA shares responsibility for animal research with any other institution. This includes the use of an external IACUC and any collaborative arrangements for support, housing, or use of animals in research. *[1200.07 (8.b(1)); Guide, p. 15]* ▶ Name(s) of other institution(s) and the date(s) on which current formal written understanding(s) took effect: 2/25/2011		X			
B. General IACUC Function						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
150	The official appointment of each member of the IACUC by the CEO *[PHS (IV.A.3a); 9 CFR (2.31(a))]* is documented and specifies the duration of the appointment and any specific role to which the member is appointed. *[1200.07 (8.a)]*		X			
151	The IACUC has at least five members, including at least one member qualified for and appointed to each of the required roles. *[PHS (IV.A.3); Guide (p. 24)]*		X			
152‡	The IACUC meets as necessary to fulfill responsibilities. *[Guide (p.25)]*		X			
153	The IACUC has adequate authority, administrative support, and other resources to fulfill its responsibilities. *[Guide (p. 14-15)]*		X			
154†	The IO has authority to allocate needed resources. *[Guide (p.13)]*		X			
155	The IACUC communicates regularly with the R&D Committee, by providing the R&D Committee with a set of final, signed, IACUC minutes, and all other notifications required by the R&D Committee, and through an individual who regularly attends meetings of both the IACUC and the R&D Committee. *[1200.07 (8.h (2)); 1200.01 (11.f)]*		X			
156†	Program needs are regularly communicated to the IO by the AV and/or the IACUC. *[Guide (p. 13)]*		X			
157	The IACUC communicates effectively as needed with the SRS and/or the IBC. *[1200.07 (Appendix C-8.a)]*		X			
158	All minority opinions that are submitted are included in the final document that results from any action of the IACUC (e.g., meeting minutes, report of semiannual evaluation, and reports to oversight entities). *[PHS (IV.B.); 9 CFR (2.31(c)(3))]*		X			
159	The research office provides packets to IACUC members no later than 3 business days before the IACUC meeting. This packet must include an agenda with all business items listed, including reviewer assignments for all new protocols. *[1200.07(8.f(2)(d))]*		X			

▶ Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
▶ Station Number: 671
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▶ Date of Semiannual Evaluation: June 28, 2018

160	A written draft of the minutes of the latest IACUC meeting is provided to all IACUC members at least 1 week before the next meeting.		X			
161	Review and approval by the IACUC is required before any work related to the use of animal subjects in VA research begins or is changed significantly. *[1200.07(8f(2)); PHS (IV.B.6-7); 9CFR (2.31(c)(6-7)); Guide (p. 26)]*		X			
162	All protocol forms used comply with PHS Policy and USDA AWAR. *[PHS(IV.C);9 CFR (2.31(d))]*		X			
163	The current version of the VA ACORP (or an alternate form that has been approved by the CVMO) is used for any protocol involving work to be supported with VA funding. *[1200.07 (8.f(2)(e))]*		X			
164‡	Consultation with a qualified laboratory animal veterinarian is required before a protocol may be submitted for review by the IACUC. Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol.*[1200.07 (Appendix D - I.k(2)); 9 CFR (2.31(d)(1)(iv)(B)); Guide (p.5)]*		X			
165‡	No IACUC member participates in the review or approval of any protocol in which that member has a real or apparent conflict of interest (financial or otherwise). *[Guide (p. 26)]*		X			
166	The IACUC does not approve any protocol that involves use of hazardous agents until the Biosafety Official and/or the Radiation Safety Official, as applicable, has signed in Item Z to confirm that the hazardous agents are properly documented in the ACORP.. *[1200.07 (Appendix C-.8.c(1)); Guide (p. 21)]*		X			
167	Use of any patient care area for VA-funded animal research is prohibited unless the IACUC and appropriate local clinical and administrative officials first grant approval and the IACUC has reviewed and approved a completed ACORP Appendix 7 that justifies no reasonable alternative to the use of human clinical areas or equipment exists. *[1200.07 (7.k(1))]*	X				
168†	A system of post-approval monitoring is in place to ensure that all work with research animals is performed according to IACUC approved protocols. *[Guide (p. 33)]*				X	
169	The IACUC conducts continuing reviews of all protocols annually. *[9 CFR (2.31(d)(5))]*		X			
170	IACUC approval of each protocol expires on or before the third anniversary of its initial approval. *De novo* review and approval of a complete updated protocol by the IACUC before the date of expiration is required for work on the protocol to continue beyond three years without interruption. *[PHS (IV.C.5)]*		X			
171	Humane endpoints are established for studies in which pain and/or distress is anticipated (i.e., tumors, infectious disease, vaccine challenges, trauma, etc.) *[Guide (p.27)]*		X			
172	The IACUC has established oversight procedures for pilot and field/wildlife studies; studies involving genetically modified animals, food/fluid restriction, and the use of pharmaceutical versus non-pharmaceutical grade chemicals receive special consideration by the IACUC. *[Guide (p. 27-33)]*		X			

▶ Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
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173	Surgical procedures are determined to be major or minor, multiple surgical procedures on a single animal are justified and the outcome evaluated, and multiple survival procedures regardless of species conform to regulated species standards. *[Guide (p.30)]*		X			
174‡	Requests for exemptions from major survival procedure restrictions are made to the USDA/APHIS through the IO. *[Guide (p. 30)]*.	X				
175	Toe-clipping is approved by the IACUC only when no other individual identification method is feasible; the procedure is performed aseptically and with pain relief. *[Guide (p.75)]*		X			
176‡	The use of restraint devices is justified in the animal use protocols. IACUC approval is given when the purpose and duration of the restraint are justified. The justification addresses: the lack of feasible alternatives to physical restraint, provisions for the removal of maladaptive animals, training of animals, and appropriate observation of restrained animals. Veterinary care is provided if lesions or illness associated with restraint occur. *[Guide (p 29-30)]*		X			
	C. Semiannual Evaluations of the Animal Care and Use Program					
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
200	Program Review -- At least every six months, the IACUC reviews the animal care and use program. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8,f(1)); PHS (IV.B.1); 9CFR (2.31(c)(1))]*		X			
201	Facilities Inspection -- At least every six months, the IACUC inspects all facilities in which animals in the VA animal research program are used. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8,f(1)); PHS (IV.B); 9CFR (2.31(c)(2))]*		X			
202	Under no circumstances is the report of any semiannual evaluation altered after it has been signed by the IACUC. *[1200.07 (8,f(1)(f))]*		X			
203	The report of each semiannual evaluation of the animal care and use program, signed by the IACUC, is discussed personally with the Director of the VA facility in a meeting with at least one representative voting member of the IACUC. *[1200.07 (8,f(1)(e)); PHS (IV.B); 9 CFR (2.31(c)(5); Guide (p. 25)]*		X			
204	Within 60 days of approval by the IACUC, the report of each semiannual evaluation, signed by the facility Director, is submitted to the CVMO (ORD), or the CVMO's office is notified of the reason for delay and the expected date of submission. *[1200.07(8,k(3))]*		X			
	D. Standard Operating Procedures (SOPs)					
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency

▶ Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
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250	At least annually, the IACUC oversees a review of the complete set of all local SOPs by the Attending Veterinarian with the VMU supervisor and other qualified personnel. *[1200.07 (7.c)]* ▶ Date of latest review:		X			
E. Addressing Concerns about Animal Welfare						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
300‡	The responsibility for animal well-being is assumed by all members of the program; therefore, procedures are in place for the IACUC to receive, review, investigate, and address internal or external concerns or allegations about animal care and use. *[PHS (IV.B); 9 CFR (2.31(c)(4)); Guide (p. 1;23-24)]*		X			
301	Procedures are in place to protect "Whistle-blowers" from discrimination or reprisal for reporting potential regulatory violations within the animal care and use program. *[9CFR (2.32(c)(4)); Guide (p. 24)]*		X			
302	Any animal activity may be suspended by the IACUC (by a majority vote of a quorum), or immediately and unilaterally by the facility Director or any other official designated by the facility Director. *[1200.07 (8.)); 9 CFR (2.31(c)(8) and 2.31(d)(6))]*		X			
303	The IACUC notifies local administrators (facility Director, RCO, ACOS/R&D) and external oversight entities (CVMO, ORO, OLAW, and AAALAC) immediately when an investigation is undertaken. *[1200.07 (8.i)]*		X			
304	Within 5 business days of determining that a reportable deficiency has occurred, the IACUC submits an initial report to the facility Director and the IO, with copies to the ACOS/R&D and other relevant research review subcommittees. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
305	Within 5 business days (*ORO requirement*) of receiving a report of a reportable deficiency from the IACUC, the facility Director and IO submit the report to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
306	The corrective action plan, the timetable for its implementation, and interim and final reports on the correction of each reported deficiency are submitted to the facility Director and IO, and through them to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1200.07 (8.l)]*		X			
F. Reporting to Oversight Entities						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency

▶ Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
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350	The USDA Annual Report of Research Facility was completed and submitted by December 1 within the past year, as required by USDA, and a copy is on file locally. *[9CFR (2.36)]* ▶ Date of most recent submission: **10/10/2017**		X			
351	The VA facility is covered by a PHS Assurance, approved by OLAW, and revised as needed to reflect any significant changes in the animal care and use program. *[PHS (IV.A)]* ▶ Name of the Institution that holds the PHS Assurance: ▶ Effective date of most recent approved Assurance: **3/4/2015**		X			
352	The annual report to OLAW was submitted within the past year by the end of the month immediately following the end of the last reporting period, and a copy is on file locally. *[PHS (IV.F.1-2)]* ▶ Date of most recent submission: **1/2018**		X			
353	The VA facility is fully accredited by AAALAC, and a copy of the triennial comprehensive AAALAC Program Description is on file locally. *[1200.07 (7.e)]* ▶ Name of the Institution that holds the accreditation: **STVHSCS/VMU**		X			
354	The AAALAC Annual Report was submitted within the past year as required by AAALAC, and a copy is on file locally. *[1200.07 (8.I(2)(b))]* ▶ Date of most recent submission: **1/9/2018**		X			
355	The VA Veterinary Medical Unit (VMU) annual report, which includes mice and rats, was submitted online by the specified deadline (usually January 15) within the past year. *[1200.07 (8.I(4))]*		X			
356	All other correspondence with oversight entities (USDA, OLAW, AAALAC, and ORO) relevant to the animal research program (except for routine notifications and reminders) is copied to the CVMO within 15 days of receipt or submission. *[1200.07 (9)]*		X			
357	All documents relevant to the animal care and use program are maintained on file for at least three years, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. This includes acquisition/disposition records, IACUC meeting minutes, semiannual reports, and all reports to, and correspondence with, oversight entities. *[1200.07 (Appendix E-2. c); 9CFR2.35(f); PHS (IV.E)]*		X			
358	All documents relevant to individual studies are maintained for at least the duration of the study and for three additional years after the completion of the study, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. *[1200.07 (8.f(1)(b)); 9CFR2.35(f); PHS (IV.E)]*		X			
G. Personnel Qualifications and Training						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
400‡	The IACUC does not approve any protocol until each individual listed on the protocol has documented completion of required VA training at the prescribed intervals. *[1200.07 (8.m(1)); PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 15); US Government Principle VIII)]*		X			

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401‡	The IACUC confirms that each individual is appropriately trained before approving that individual to perform the procedure without supervision. This includes non-surgical and surgical procedures, anesthesia monitoring, and euthanasia. *[PHS (IV.C.1.f); 9 CFR (2.31(d)(1)(ii)); Guide (p. 15 & 115)]*		X			
402‡	All personnel are documented as being appropriately trained for their positions, and participating in formal and/or on-the-job continuing education at the prescribed intervals. *[1200.07 (8.m); PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 16-17)]*		X			
403†	IACUC members receive training in all aspects of humane animal care and use through the documented completion of VA training at the required intervals. *[PHS (IV.A.1.g); 9 CFR (2.32); 1200.07 (8.m); Guide (p.17)]*		X			
	H. Occupational Health and Safety					
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Occupational Health and Safety Program (OHSP)						
450‡	An OHSP has been established and is maintained by the VA facility to protect personnel involved in animal research (laboratory or field setting) from associated risks including but not limited to direct animal contact, exposure to unfixed tissues or fluids, hazardous agents used in the research, etc. *[PHS (IV.A.1.f); Guide (p.17; 32); 1200.07 (10)]*		X			
451	All personnel at risk of exposure have the opportunity to participate in the OHSP. This includes personnel whose duties include work with animals (e.g., VMU staff, investigators, research technicians), regardless of whether they are paid employees, without compensation (WOC) personnel, students, or trainees, as well as , personnel that do not have contact but are exposed to animals (e.g., maintenance and engineering staff assigned to the VMU, other service personnel, etc.). *[1200.07 (10.a); Guide (p. 18)]*		X			
452	**Hazard Identification and Risk Assessment** – The IACUC, the local veterinarians, the SRS, and the Safety Officer work together effectively to identify potential hazards that exist in the animal research program, to assess the consequent risks to personnel, and to determine appropriate strategies to manage the risks. *[Guide (p. 18-19)]*		X			
453	**OHSP Training** – Training is provided to all personnel covered by the OHSP, with regard to personal hygiene practices, use of safety equipment, and SOPs appropriate to each individual's duties and risks of exposure. *[Guide (p. 20)]*		X			
The OHSP – Facilities and Procedures						
454	**Ergonomic efficiency** – Procedures and policies are in place to reduce the risks of ergonomic injuries to personnel (e.g. facility design, SOPs, and the use of equipment such as ramps, carts, and hydraulic lifts). *[Guide (p.19- 20)]*		X			

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455	**Control of exposure** – Personal exposure to hazardous agents is limited through the design of the facility, establishment of SOPs (e.g. separation of animals treated with hazardous agents from untreated animals), selection/maintenance/certification of safety equipment (e.g., showers, eyewash stations, fume hoods, etc.), and careful monitoring of agents to ensure that they remain within permissible ranges. *[Guide (p. 19-20)]*		X			
456	**Policies and Procedures associated with nonhuman primates (NHPs)** – have been established and include training with regard to the risks of exposure to *Macacine herpesvirus 1* (formerly *C. herpesvirus* or Herpes B virus); tuberculosis screening for exposed personnel; training on and the handling of bites, scratches, or other injuries; medical evaluation and treatment of injuries; and provision of appropriate PPE. *[Guide (p. 23)]*	X				
The OSHP – Personal Hygiene						
457	The OHSP includes guidelines on appropriate personal hygiene practices, including hand washing and showering, use of protective clothing, and restricting consumption of food and beverages to designated break areas. *[Guide (p. 20-21)]*		X			
458	The VA facility provides uniforms, laundry service, and all other necessary personal protective equipment (e.g., gloves, ear protection, protective eyewear, steel-toed footwear, respirators, with appropriate fit testing and training, and other special equipment), as appropriate to the duties of the personnel. *[Guide (p. 20-23)]*		X			
The OHSP – Medical Evaluation and Preventive Medicine for Personnel						
459	A pre-employment medical evaluation is performed on each prospective new employee. *[1200.07(Appendix C-4(2)(a))]*		X			
460	A follow-up medical evaluation is performed at routine intervals (usually annually) on each OHSP participant. *[1200.07(Appendix C-4(2)(b))]*		X			
461	Enrollment in OHSP is prerequisite to approval for access to the VMU and for beginning work with animals. *[1200.07(Appendix C-4(2)(c))]*		X			
462	Personnel are not permitted to decline immunizations or tests required by the VA facility that are necessary to protect the health of the animals or personnel. *[1200.07 (10.b)]*		X			
463	All vaccines (e.g., tetanus, rabies) are provided to personnel as currently recommended by CDC, free of charge. *[1200.07 (10.f(2)); Guide (p. 23)]*		X			
464	Personnel are required to report and be treated for all injuries and illnesses potentially related to working in the VMU or other animal research areas, or otherwise in connection with work with animals. *[1200.07(Appendix C-4.b; Guide (p. 23)]*		X			
465‡	The program considers confidentiality and other legal factors as required by federal, state and local regulations. *[Guide (p. 22)]*		X			
466‡	If serum samples are collected, the purpose is consistent with federal and state laws. *[Guide (p. 22)]*	X				

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II. Physical Plant

A. General						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
500	The physical plant infrastructure (includes HVAC, plumbing, lighting, power, control systems, etc.) is adequate to support the needs and performance standards of the animal care and use program, and is compliant with and meets all applicable building codes. *[Guide (p. 133-136)]*		X			
501	Policies and procedures are in place to ensure that facilities and equipment are properly maintained and functional. *[Guide (p. 133-136)]*		X			

III. Operations Related to Animal Environment, Housing, and Management

A. Physical Environment						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Temperature, Humidity, and Ventilation						
550	The response of facilities management (FM) personnel to elevations in temperature in animal rooms is tested and reported to the IACUC at least annually, and the response by FM personnel is satisfactory. *[1200.07 (7.a(2)(c))]*. ▶Date of latest test: **10/5/2017**		X			/
551	HVAC reheat units serving animal rooms are designed so as to fail in the "off" position, preventing over-heating of animals. *[1200.07 (7.a(2)(a))]*		X			
Noise						
522	Policies are in place to minimize exposure of the animals and personnel to excessive vibration, unnecessary sounds, and any sounds louder than 85dB. *[Guide (p.49-50)]*		X			
B. Husbandry						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
General						
600‡	Oversight of daily husbandry and other animal care duties has been assigned to a single individual (usually, the VMU Supervisor) when a full-time veterinarian is not available on site. *[Guide (p. 1-4)]*		X			
Population Management						

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601	Methods of animal identification have been established, which provide the protocol number and other pertinent information. Where applicable, genotype information is provided using accurate, consistent, and unambiguous genotype nomenclature. *[Guide (p. 75-77)]*		X			
Behavioral Management						
602	**Activity** – Each animal must have opportunities to engage in activity (motor, cognitive, and social) appropriate to its species. *[Guide (p. 60):63)]*		X			
603	**Social Environment** – Animals must be housed in appropriate compatible social groups or when single housing of social species is required (by an approved protocol or because of veterinary concerns) have contact with compatible conspecifics and/or enrichment. *[Guide (p.51. 63-65)]*		X			
604	**Environmental Enrichment** – The program to enrich the structural environment of each animal (structural additions, exercise, manipulative activities, and cognitive challenges) to accommodate the expression of species-typical postures and behavior is reviewed regularly by the IACUC, researchers, and veterinarians. *[Guide (p. 52-54)]*		X			
C. Animal Procurement and Transportation						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
650‡	Only animals that are obtained lawfully may be used in VA research. *[1200.07(7.b(1)): Guide (p.106)]*		X			
651	Animal procurement is approved and initiated only after confirmation that: (1) the source of animals is appropriate; (2) appropriate housing and care for the animals upon arrival is coordinated with animal care staff; and (3) the animals are designated for use on an IACUC approved protocol. *[Guide (p. 106-109)]*		X			
652‡	Transportation (including intra-institutional, inter-institutional, interstate, international, and from commercial or non-commercial sources) complies with federal and international regulations, as applicable, and is arranged to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[Guide (p. 107): 9 CFR (Part 3, Standards)]*		X			
D. Preventive Medicine						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
700	The institutional animal care and use program strives to maintain research animal populations that are as free of infectious agents as possible. *[1200.07 (7.d(1))]*		X			

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701	A program of veterinary care, overseen by a VMO or VMC, is in place for the surveillance, diagnosis, treatment, and control of non-protocol diseases or conditions (especially those with zoonotic potential, such as Q-fever, LCMV, parasites, etc.), and for the management of diseases or conditions induced by experimental requirements. *[Guide (p. 112-114)]*		X			
702	Quarantine and stabilization of newly received animals, as well as, separation of animals by species, source, health status, and intended use, as appropriate, are used to prevent spread of pathogens. *[Guide (p. 109-112)]*		X			
E. Waste Disposal						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
750	Procedures are in place for sanitation of waste containers, as well as procedures for safe removal and disposal of conventional, biological, and hazardous wastes (including soiled bedding). All waste disposal procedures comply with facility, municipal and federal policies and regulations. *[Guide (p. 73-74)]*		X			
F. Pest Control						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
800	A regularly scheduled and documented program of monitoring for and controlling pests has been implemented, which includes measures to prevent vermin entry and harborage. *[Guide (p. 74)]*		X			
801	Animal and human health concerns encourage the use of non-toxic methods of pest control instead of chemical pesticides whenever possible. If chemical pesticides are to be used, the investigators whose animals may be exposed are consulted to ensure that scientific objectives are not unnecessarily compromised. *[Guide (p.74)]*		X			
G. Medical Supplies						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
850	All controlled substances needed for animal research on VA property are ordered and received by the local VA pharmacy, and dispensed to research personnel as needed. *[1200.07 (7 m)]*		X			
851	Use of non-pharmaceutical grade compounds, expired drugs or medical supplies (e.g., sutures, antiseptics, etc.) in animals is limited to protocols in which such use has been documented not to jeopardize animal welfare or compromise the validity of the study. *[PHS (FAQ F.4); Guide (p.31)]*		X			
H. Emergency, After Hours, Weekend, and Holiday Animal Care						

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
900	Qualified personnel are assigned to provide routine care for the animals on weekends and holidays. *[Guide ((p. 74): 9 CFR (2.33(b))]*		X			
901	Veterinary care is available as needed after regular work hours on weekends, and on holidays; procedures are in place for timely notification of a veterinarian in case emergency care is needed. *[Guide (p. 74): 9 CFR (2.33(b))]*		X			
902‡	A disaster plan that addresses the needs of both personnel and animals is in place including animal euthanasia if necessary; the plan is approved by the IACUC. *[Guide (p. 35;75)]*		X			
903†	The disaster plan addresses triage procedures, emergency/life support services; preservation of irreplaceable animals, essential personnel, and disaster response training. The animal facility plan is approved by institution, is a component of the overall disaster plan, and is provided to first responders. *[Guide (p. 35; 75)]*		X			
904	Key animal facility personnel (e.g., the Attending Veterinarian and the VMU supervisor) are included among the official responders to be contacted in emergencies that involve animals. *[Guide (p.75)]*		X			

IV. Veterinary Medical Care

A. Role of the Veterinarians						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
950 ‡	A high quality veterinary care program consistent with ethical standards has been established. *[Guide (p. 105)]*		X			
951 ‡	Each VMO and VMC has training and/or experience in lab animal medicine and with the species used. *[Guide (p. 15); 9 CFR (2.33)]*		X			
952†	The VMOs and VMCs provide guidance to research personnel with regard to the humane care and use of the animals in the context of the scientific and regulatory requirements (including appropriate handling of animals, sedation, anesthesia, surgery and peri-operative care, analgesia, and euthanasia). *[Guide pg 105-106, 113-114; 9 CFR (2.31(d)(1)(iv)(B) and 2.33(b)(4-5))]*		X			
953	When veterinary care services are provided by a part-time or consulting veterinarian, the veterinarian's visits are of sufficient frequency to meet programmatic needs. A written program of veterinary care for USDA regulated species is in place if a full-time attending veterinarian is not on-site. *[Guide (p. 14):USDA-APHIS Policy #3]*		X			

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954 ‡	Veterinary care is available as needed and effective procedures are established for timely reporting of animal injury, illness, or disease and for veterinary assessment, treatment, or euthanasia. The veterinarian is authorized to treat, relieve pain, and/or euthanize. *[Guide ((p. 106, 113, 114, 120, and 122-123); 9 CFR (2.33(b))]*		X			
955 ‡	The Attending Veterinarian has the authority and resources needed, and uses them appropriately to manage all aspects of animal care and use in the animal research program. *[Guide (p. 14); 9 CFR 2.33(a)(2)]*		X			
956 ‡	Veterinary access to all animals is provided. *[Guide (p. 14)]*		X			
B. Surgery						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
1000	Aseptic technique is required for all survival surgery; is appropriate to the species; and includes preparation of the patient, surgeon, sterile materials, and supplies, as well as appropriate operative technique to reduce the risk of infection. *[9CFR (2.31(d)(1)(ix); Guide (p.118-119)]*		X			
1001	Procedures are in place to ensure that appropriate surgical anesthesia and analgesia are provided. Postoperative monitoring and care are provided by trained personnel and documented. *[Guide (p. 119-120)*		X			
1002	Major surgical procedures in non-rodents may be performed only in dedicated surgical facilities. *[9CFR (2.31(d)(1)(ix))]*	X				
1003	A system of ongoing and thorough assessment of surgical outcomes is in place to ensure that appropriate procedures are followed and appropriate corrective changes are implemented in a timely manner. *[Guide (p. 115)]*		X			
1004	Pre-surgical planning includes veterinary input and addresses location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping, etc. *[Guide (p 116)]*		X			
1005	For non-survival surgery, the surgical site is clipped, gloves are worn, and the surgical area and instruments are clean. *[Guide (p.118)]*		X			
C. Pain, Analgesia, and Anesthesia						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
1050	Guidelines for the assessment and management of pain, distress, and animal wellbeing have been established, and include monitoring for effectiveness of pain control, consideration of non-pharmacologic pain control methods, and guidance regarding the selection and use of anesthetics and analgesics. *[Guide (p. 121-122)]*		X			
1051 ‡	Procedures are in place to assure anti-nociception before surgery begins. *[Guide, p 122)]*		X			

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1052	Special precautions for the use of paralytics are in place to ensure adequate anesthesia. *[Guide (p 123)]*	X				
1053 ‡	The drug storage and control program complies with federal regulations for human and veterinary drugs; procedures have been established to ensure that analgesics and anesthetics are used prior to their expiration date. *[Guide (p.115)]*		X			
1054 †	Anesthetics and analgesics are acquired, stored, and disposed of in a legal and safe manner; drug records and storage procedures are reviewed during facility inspections. *[Guide, p. 115 & 122)]*		X			
D. Euthanasia						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1100	The methods of euthanasia approved by the IACUC are consistent with the AVMA recommendations for the species involved. *[Guide (p. 123); PHS (IV.C.1.g); 9 CFR (2.31(d)(1)(xi))]*		X/			
1101	Personnel receive training on euthanasia methods appropriate for the species and age of the animal to minimize the potential for pain and distress. *[Guide (p. 123-124)]*		X			
1102 ‡	Procedures and training are in place to ensure that death is confirmed. *[Guide (p. 124)]*		X			

V. Animal Care and Use Program Work Orders

Instructions: Enter work order data as prompted for Tables 1 and 2. All work orders related to the animal care and use program should be entered, whether or not they resulted from a semiannual evaluation. Use Table 3 to summarize the work orders in Tables 1 and 2.

Table 1: Work Orders Completed - include all work orders completed since the previous semiannual program evaluation (▶Date(s) of previous evaluation:).

#	Enter M, S, or No, for Minor or Significant deficiency noted in semiannual evaluation, or Not related to semiannual evaluation	Work order (local reference) number	Summarize work requested	Date work order was submitted	Date work order was completed	Elapsed days from submission to completion
1	Not		(b)(6) Water faucet has a leak	12 Feb 18	13 Feb 18	1
2	Not		Replace outlet cover	12 Feb 18	15 Feb 18	3
3	Not		(b)(6) repair hallway wall trim	20 Mar 18	21 Mar 18	1
4	Not		Sand, seal, and paint various doors	4 Jun 18	15 Jun 18	11
5						

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Table 2: Work Orders Not Yet Completed - Include all open work orders generated by previous semi-annual evaluations and other sources. Work orders placed as a result of the current semi-annual review are also entered below.

#	Enter M, S, or No, for Minor or Significant deficiency noted in semiannual evaluation, or Not related to semiannual evaluation	Work order (reference) number	Summarize work requested	Date work order was submitted	Elapsed days from submission until _____ (enter date used to calculate elapsed days)
1	Not		Replace all ceiling tiles (b)(6)	6 June 17	386
2					
3					
4					
5					

Table 3: Summary

Table #	Number of work orders entered	Average days elapsed
1	4	4
2	1	386

Comments (provide any additional information relevant to the numbers of days required for completion of the work orders submitted):

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section B. Inspection of the Facilities

The Inspection of the Facilities focuses on a physical and visual evaluation of buildings, equipment, and the environment in which animals are maintained and utilized. Some of the items here appear similar to items included in Section A (Review of the Program), but the focus here (Inspection of the Facilities) is on what is actually observed in the animal facilities, while Section A focuses on what is intended or designed.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted:

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee",
"1200.07" refers to the "VA Handbook 1200.07, Use of Animals in Research",
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
   (Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities be completed every 6 months *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]*. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "▶" symbols indicate required information:

▶Date(s) of the most recent previous Inspection of the Facilities: December 6, 2017
▶Date(s) on which this Inspection of the Facilities was conducted: June 14, 2018

Names of voting IACUC members who participated in the Facility Inspection:
(The Facility Inspection team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

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Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b)(6)	(b)(6)	
(b)(6)		6/28/18
(b)(6)		6/14/18
		6/14/18 & 6/28/18

Non-IACUC members who participated in the Facility Inspection:

Name	Title	Date(s) of Participation
(b)(6)	(b)(6)	6/14/18

3) The IACUC must inspect semiannually all units of the animal care and use program, including the following:
all areas within the VA animal facilities;
all spaces outside the VA animal facilities where animals are housed for > 12 hours;
any areas where any procedure is performed on animals.

Identify each unit subject to inspection (press Tab in bottom right cell to add rows to the table):

Location (name of site, building name and room number, etc.)	**Species**	**Type of Space** (e.g., (b)(6) satellite, investigator laboratory) **and the Nature of the Procedures Performed** (e.g., housing, terminal surgery, behavioral training, etc.)	**Name and Role** (e.g., (b)(6) (b)(6) PI) **of Responsible Individual**
(b)(6)	Mice/Rats	(b)(	(b)(6) (b)(6)

4) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (approved by the IACUC)
Minor Deficiency
Significant Deficiency
Could Not Evaluate (during this inspection)

The last line of each section of the checklist is designated "Other Observations", for documentation of relevant observations that are not directly addressed by the checklist items.

5) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section B), provide details in Part 2 of this form.

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6) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡ **denotes a new "must" item**

† **denotes a new "should" item**

I. Implementation of Institutional Policies

A. Performance of Work According to Protocol

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1150	Current versions of IACUC approved protocols are readily available to animal care staff as well as research staff.		X				
1151	Animal research procedures (observed by the IACUC inspection team includes but is not limited to conduct of surgery, behavioral testing, training, exercise, administration of anesthetics and analgesics, etc.) are being performed according to the protocols approved by the IACUC. *[PHS (IV.C.1); Guide (p. 33-34)]*		X				
1152	Individuals observed working with animals are identified on the corresponding protocols approved by the IACUC.		X				
1153	Routine husbandry tasks observed are being performed according to documented SOPs.		X				

B. Addressing Concerns about Animal Welfare

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1200	Contact information for responsible local and VA Central Office personnel are posted prominently in the animal facility for reporting of animal welfare concerns. *[1200.07 (8.k(2)). Guide (p. 24)]*		x				

C. Occupational Health and Safety

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1250	Appropriate hazard signs and relevant safety protocols are posted in plain view, and the MSDSs are readily available, where specific hazardous agents are in use. *[1200.07 (Appendix C-8.h(1)-(2))]*		X				
1251	Wherever gas anesthetics are used, waste anesthetic gas is removed via a scavenging system or by another approved method. *[Guide (p. 21; 145)]*		X				
1252	Labels on safety equipment (e.g. eye wash, emergency shower, fume hoods, etc.) indicate that maintenance and certification are current. *[Guide (p. 20)]*		X				
1253	Good safety practices are evident as indicated by proper glass and sharps disposal, gas cylinders appropriately secured, proper separation of chemicals and wastes, etc. *[Guide (p.74)]*		X				

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1254	Supplies are readily available for treatment of bites, scratches, and puncture wounds according to current CDC recommendations. *[Guide (p. 23)]*		X				
1255	Adequate supplies of appropriate attire and clean protective clothing, including disposable PPE (e.g. gloves masks, shoe covers, etc.) are readily available; soiled items are disposed of, laundered, or decontaminated according to approved facility procedures. *[1200.07(Appendix E-2.e) :Guide (p. 20-22)]*		X				
1256	The IACUC inspection team determined that with regard to the use of hazardous agents, appropriate procedures, containment equipment, and personal protective equipment are used to safeguard personnel and animal health and are consistent (where applicable) with APHIS, USDA, and CDC Select Agent Regulations and other federal, state, and local regulations including security measures. *[1200.07 (Appendix E-2(l)); Guide (p. 20-22; 148-149)]*		X				

D. Other observations

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1300							

II. Physical Plant

A. General

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1350	Corridors are sufficiently wide and clear of obstacles so that personnel and equipment can move easily without impediment. *[Guide (p. 136)]*		X				
1351	Floor surfaces are moisture-resistant, nonabsorbent, and impact-resistant; floors are in good condition, without cracks, evidence of delamination or deterioration, of appropriate texture, and are clean and sanitized. *[Guide (p. 137-138): 9 CFR (Part 3, Standards)]*				X		
1352	Floors slope appropriately to drains; drains are filled with liquid, and those not in use for long periods are capped/covered. *[Guide (p. 138)]*		X				
1353	Wall and ceiling surfaces are smooth, moisture-resistant, nonabsorbent, impact-resistant, washable, and free of unsealed penetrations. These surfaces were found to be clean, sanitized according schedule, free of defects and evidence of water damage. *[Guide (p. 138-139): 9 CFR (Part 3, Standards)]*		X				

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1354	Doors are adequately sized, fit tightly within their frames, are sealed to prevent vermin entry, and are in good repair; preferred features include self-closing mechanism, sweeps, recessed handles, and protective hardware. *[Guide (p. 137)]* Note: With the exception of doors with viewing windows that are needed for safety and other reasons, windows in animal facilities should generally be avoided.) *[Guide (p. 137)]*		X				
Heating, Ventilation, and Air-Conditioning (HVAC) System							
1355	Maintenance of temperature, humidity, and air pressure differentials within recommended ranges throughout the facility is documented. *[Guide (p. 43-47)]* ▶ List the document(s) reviewed:		X				
1356	HVAC reheat units serving animal rooms fail in the "off" position, as designed, to prevent over-heating of animals. *[1200.07 (7.a(2)(a))]*		X				
1357	Effective back-up mechanisms are in place to maintain temperatures and humidity within acceptable ranges in the event of an electrical outage or failure of the HVAC system in the animal research facility. *[Guide (p. 141)]*		X				
Power & Lighting							
1358	Moisture-resistant switches and outlets, and ground-fault interrupters, have been installed in wet areas (e.g. cage processing, aquatic holding areas, etc.) *[Guide (p. 141)]*		X				
1359	Light fixtures, timers, switches, and outlets are properly sealed to prevent vermin from being harbored in them. *[Guide (p. 141)]*		X				
1360	Protective covers are in place over light bulbs and light fixtures. *[Guide (p. 141)]*		X				
1361	In the event of a power failure, alternative or emergency power supply is available to maintain critical services. *[Guide (p. 141)]*		X				
Noise Control							
1362	Noise reduction practices are utilized. *[Guide (p. 49-50; 142)]* For example: • Entry doors from corridors to animal housing areas are closed when not in use. • Carts, racks, and other equipment are equipped with casters. • Noisy animals are grouped in one section of the animal facility. • Sound-generating equipment is selected and located to minimize disturbance to animals		X				
1363	Vibration dampening procedures are practiced where applicable. *[Guide (p. 142)]*		X				
Environmental Monitoring							
1364	Environmental conditions in animal holding spaces and other sensitive areas are monitored and verified by one or more mechanism or systems. *[Guide (p. 143)]*		x				
B. Facilities for Sanitization							

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1400	A dedicated cage and equipment processing area of appropriate size and design (including safety features, traffic flow, utilities, egress, HVAC capacity, clean storage, etc.) is available and meets program needs. *[Guide (p. 143)]*		X				
1401	Appropriate safety precautions and equipment are in place and in use; including but not limited to protective clothing and equipment, posting of standard operating procedures and warning signage, eyewash/shower stations, and functioning safety devices to prevent trapping of personnel inside of walk-in equipment (e.g., cage/rack washers, bulk sterilizers). *[Guide (p. 143)]*		X				
1402	Cage wash temperatures and sterilizer effectiveness are monitored and appropriate records are maintained. *[Guide (p. 72-73)]*		X				
	C. Storage Areas						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1450	Food and bedding, toxic or hazardous agents, and wastes are stored in separate designated areas. *[Guide (p. 141)]*		X				
1451	Food and bedding is stored in a vermin-free area and is protected from contamination. Temperature and humidity conditions are appropriate in food storage areas. *[Guide (p. 141)]*		X				
1452	Food stuffs/diets are obtained from reputable vendors and are managed to maintain quality *[Guide (p. 65-67)]*: • Feed bag stocks are rotated and used prior to expiration date or discarded. • Open bags of feed are stored in sealed, vermin-proof containers. • The storage area is clean and orderly; feed bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation.		X				
1453	Bedding bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation. Autoclaved bedding has been allowed to dry before use or storage. *[Guide (p. 69)]*		X				
1454	Refrigerated storage for animal carcasses and tissue waste is at <7°C (44.6 °F). *[Guide (p. 143)]*		x				
	D. Facilities for Aseptic Surgery						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate

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1500	Are located and designed to minimize traffic and/or contamination; the facilities include areas for surgical support, animal preparation, surgeon scrub, operating room and postoperative recovery that separate the related non-surgical activities from the operating room. Equipment and services needed to support the use of the surgery facility are available. *[Guide (p. 144-145)]*		X				
1501	Procedures are in place and have been implemented to assure effective sanitation of the operating room, surgical instruments and equipment, appropriate management and use of stored sterile supplies, scavenging of anesthetic gases, monitoring of drug inventory, and recordkeeping for anesthesia and postoperative care. *[Guide (p. 115; 122; 144-145)]*		X				
1502	Equipment needed to support aseptic surgery (e.g., autoclaves, anesthetic vaporizers, etc.) are in good repair and certifications are current. *[Guide (p. 20)*		X				
	E. Special Facilities *(include barrier, aquatics laboratory study areas, procedure areas, imaging, core service facilities ,etc.)*						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1550	Where applicable, the facility/room has appropriate drug storage/monitoring, sharps disposal, anesthetic monitoring and scavenging, safety equipment/procedures (safety signage, eyewash stations, secured gas cylinders, etc.) and carcass disposal. *[Guide (p.19-21;73-74;115;120;122;134)]*	X					
1551	Specialized facilities have procedures and equipment in place to minimize contamination risk. *[Guide (p. 147-150)]*	X					
1552‡	Appropriate sensors and ventilation are provided for areas where cryogen gases are used or stored. *[Guide (p 147)]*	X					
1553	Aquatic housing areas feature water impervious surfaces, slip resistant floors, ground-faulted electrical receptacles or circuits, and HVAC capacity to maintain appropriate temperature and humidity control. *[Guide (p 150-151)]*	X					
	F. Ancillary Areas						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1600	Showers, sinks, toilets, locker rooms, and break areas are available for personnel and are separate from animal holding or support areas. *[Guide (p. 19; 136)]*		X				
1601	Space for administrative and supervisory personnel, including space for staff training and education are available and separate from animal holding or animal support areas. *[Guide (p 136)]*		X				
	G. Security						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate

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1650	Perimeter doors are closed and locked. *[1200.07 (7.i)]*						
1651	Security measures are in practice and mechanisms for controlling entry into the facility function appropriately. *[1200.07 (7.i); 1200.01.9.c; Guide (p. 23;151)]*		X				
	H. Other Observations						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1700							

III. Animal Environment, Housing, and Management

	A. Physical Environment						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
Temperature, Humidity, and Ventilation							
1750	Temperature and humidity in animal rooms are within acceptable ranges. *Guide (p. 43)]*		X				
1751	Odors, ammonia levels, and drafts are all within acceptable limits; ventilation and air quality are adequate. *[Guide (p. 45)]*		X				
1752	The supply air to animal holding is 100 % outside air treated with appropriate filtration. Note: Exhaust air recycled into HVAC systems serving multiple rooms is a cross contamination risk and generally should be avoided. Exhaust air should be treated with at least 85-95% ASHRAE efficient filters prior to recycling. *[Guide (p. 45-47; 140)]*		X				
Illumination							
1753	Lighting in animal rooms is on appropriate diurnal cycles. *[Guide (p. 47)]*		X				
1754	The intensity, quality, distribution, and rates of change of intensity of the light are appropriate to the species in each room. *[Guide (p. 47-48)]*		X				
Noise							
1755	Radios and other equipment that produce unnecessary sound audible to the animals are not in use in animal rooms, except as required by approved protocols for research or enrichment. Vibration is minimized where possible. *[Guide (p. 49-50)]*		X				
	B. Husbandry						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
General							

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1800	Animals are appropriately separated by species and disease status. *[Guide (p 111)]*		X				
1801	Animal handling (observed by the IACUC inspection team) is appropriate to the species.		X				
1802	Room logs confirm that daily observation of each animal, as well as cage cleaning, feeding, and watering are performed at appropriate intervals. *[1200.07(7.c)]*		X				
1803	Special procedures (e.g., diet or water scheduling/restriction, prolonged restraint, etc.) are conducted as described in the IACUC approved protocols based on IACUC inspection team observations. *[1200.07 (Appendix D-1.a); PHS (IV.C.1); Guide (p. 27-33)]*		X				
Housing – Primary Enclosures							
1804†	Primary enclosures, cages, and shelters are appropriate (in terms of size, construction, floor space, height, etc.) for the species housed. *[9 CFR (Part 3, Standards); Guide (p. 51-57 and 55-63; the Ag Guide]* Note: • The recommended minimum rabbit cage height is16 inches; rabbit cages that are less than 16 inches in height may be used if the IACUC has determined through performance assessments that the cage is sufficient to meet the behavioral, physical, and physiological needs of the animal. *[Guide(p 58-59)]* • The recommended minimum floor space for a female mouse + litter is 51 in^2 ; trio breeding may be appropriate in a cage providing 75-82 in^2 of floor space; the IACUC should make this determination based on the outcome of performance based standards. *[Guide (p.56-58)]*		X				
1805‡	The primary enclosure allows the animal to express natural postures, turn around, access food and water, and rest away from urine and feces. *[Guide (p.56)]*		X				
1806	The primary enclosures (cages, tanks, pens, stalls, etc.) and accessories are clean, in good condition, and are free of rust and sharp edges; the enclosure provides safe species appropriate housing. *[Guide (p. 51)]*		X				
1807‡	Outdoor housing provides protection from extreme weather, conditions, the opportunity to retreat, and is adequately ventilated. *[Guide (p. 54-55)]*	X					
1808	Procedural laboratories that house animals for more than 12 hours meet the minimum standards for housing. *[1200.07 (Appendix E-3.b)]*	X					
Population Management							

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1809	Animal records (e.g., cage cards) include the following information, as appropriate *[Guide (p. 75-76); 9 CFR (2.35)]*: • Source of animals • Strain or stock (including genotype using standard nomenclature where applicable) • Name and contact information for PI • Protocol number • Pertinent dates (e.g., acquisition by facility, birth) • Number of individuals per group, when identified in groups • Age or weight • Gender • Individually identifiable features (e.g., markings, tattoos, ear • tags, neck chains, implanted microchips, etc.)		X				
1810	The IACUC inspection team determined that animal records are readily available, appropriately detailed, properly maintained, and accompany animals when transferred to another institution. *[Guide (p. 75-77)]*	X					
Behavioral Management							
1811	The IACUC inspection team determined that the environmental enrichment program is appropriate to the species, ages, and number of animals housed and is beneficial to and safe for the animals. *[Guide (p. 52-54)]*		X				
1812	Animals are housed in compatible social groups as appropriate; socially housed animals are able to escape or hide from aggressive animals, and have ready access to food and water. *[Guide (p. 51-60;63-65)]*		X				
1813	The IACUC inspection team reviewed the records of singly housed animals; *Guide* recommendations for singly housed animals are being followed. *[Guide (p. 64)]*				X		
1814	Based on the behavior observed by the IACUC inspection team, the animals are appropriately habituated to routine husbandry and experimental procedures. *[Guide (p. 64-65)]*		X				
Food							
1815	Each animal is fed uncontaminated, palatable, high quality food using a feed schedule and methods (that considers caloric management, delivery, and sanitation) appropriate to the species. *[Guide (pg. 65-67)]*		X				
Water							
1816	Each terrestrial animal has ready access to potable drinking water (quality based on periodic assessment) and the water distribution system is clean and appropriate to the species. *[Guide (p. 67-68)]*		X				
1817	For aquatic animals, the water quality is appropriate for the species. *[Guide (p. 78-79, 85)]*	X					
1818‡	In aquatic systems, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use. *[Guide (p. 78, 86)]*	X					
1819‡	The biofilter of the aquatic life support system is of adequate size to process the bioload. *[Guide (p 80)]*	X					
Bedding							

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1820	The bedding present in primary enclosures (where appropriate) is consistent with the species, facilitates good health, and meets scientific requirements. *[Guide (p. 68-69)]*		X				
Sanitation							
1821	Cleaning implements are designated for specific rooms or for areas at similar risk of contamination and are in good repair. *[Guide (p. 72)]*		X				
1822	Primary enclosures (including substrates and cage components), animal holding rooms, support spaces, etc. are cleaned and disinfected on a regular schedule consistent with the use of the area and nature of contamination. *[Guide (p. 70 -72)]*		X				
1823	The effectiveness of sanitation methods/procedures are assessed and documented. *[Guide (p. 73)]*		X				
C. Animal Procurement and Transportation							
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1850	Animals being transported are appropriately restrained, secured, and covered, to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[1200.07(Appendix E-3.a (15)); Guide (p. 107-109); 9 CFR (Part 3. Standards)]*		X				
1851	Promptly on receipt, animals are inspected by qualified personnel and moved to housing appropriate to the protocols for which they have been ordered. *[1200.07 (7.b(3)); Guide (p. 107-109)]*		X				
1852	The condition of animals on arrival indicates that transportation was consistent with USDA regulations and humane practices. *[Guide (p.107)]*		X				
D. Preventive Medicine							
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1900	Based on the observations of the facility inspection team, animals are separated by species, source, health status, intended use (as appropriate) and after receipt, the animals are allowed a stabilization period. *[Guide (p. 109-112)]*		X				
E. Waste Disposal							
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**	**Could Not Evaluate**
1950	Conventional, biological, and hazardous wastes are regularly collected, stored and disposed of through the use of safe handling and processing practices. *[Guide (p. 73-74)]*		X				
1951	Waste receptacles are leak-proof, labeled, cleaned regularly, and have tight-fitting covers. *[Guide (p. 73)]*		X				
1952‡	Hazardous wastes are rendered safe before removal from facility. *[Guide (p. 73-74)]*		X				

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1953	Appropriate containers for sharps disposal are readily available in locations in which sharps are used, and are no more than 2/3 to 3/4 full. *[Guide (p. 74)]*		X				
F. Pest Control							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2000	A humane, effective, and documented pest prevention and control program (that includes rodents and insects) is in place; there is no evidence of pests in the facility. *[Guide (p. 74)]*		X				
2001	When it is necessary to use pesticides in animal holding areas, investigators are consulted in advance of pesticide use. *[Guide (p. 74)]*		X				
G. Medical Supplies							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2050	Non-pharmaceutical grade compounds identified during the inspection were confirmed to be associated with an IACUC approved protocol. *[PHS (FAQ F.4); Guide (31)]*		X				
H. Emergency, After Hours, Weekend, and Holiday Care							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2100	The review of log sheets confirm that animals are cared for by qualified personnel on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74); 9 CFR (2.33(b))]*		X				
2101‡	Posted contact information for veterinary staff and veterinary care entries in logs confirm that emergency veterinary care is available and provided as needed after hours, on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74:114); 9 CFR (2.33(b))]*		X				
2102	Telephone numbers of key personnel are readily accessible to police and fire agencies at all times. *[Guide (p. 74)]*		X				
I. Other Observations							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2150							

IV. Veterinary Medical Care

A. General

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		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2200	Animals are observed at least daily for signs of illness, injury or abnormal behavior by trained personnel. *[Guide (p. 112)]*		X				
2201	Visits by part-time veterinarians are documented in a log showing the date and time of each visit. *[1200.07 (Appendix E-2.f(9))]*		X				
	B. Surgery						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2250	The IACUC inspection team determined that the recommendations of the *Guide* are followed for non-survival surgery (the surgical site is clipped, the surgeon wears gloves, the instruments and the surrounding area are clean). *[Guide (p. 118)]*						X
2251	The IACUC inspection team determined that aseptic technique is used for all survival surgical procedures, and includes appropriate preparation of the animal (shaving and disinfection of the surgical site), preparation of the surgeon (scrubbing, use of sterile glove, gowns, etc.), and use of aseptic operative techniques; the aseptic technique procedures are appropriate for the species used. *[Guide (p. 118-119)]*						X
2252	The IACUC inspection team determined that all surgical instruments and implants used in survival surgery are sterilized by steam, gas, or approved chemicals. Note: Alcohol is not a sterilant or a high-level disinfectant. *[Guide (p. 119)]*						X
2254	The IACUC inspection team observed that for multiple consecutive rodent surgeries, personnel using hot bead sterilizers or liquid chemical sterilants for instrument sterilization take appropriate precautions to prevent thermal or chemical burns. *[Guide (p. 119)]*						X
2255	The IACUC inspection team confirmed that the operating area is cleaned and disinfected prior to major survival surgery. *[Guide (p. 117)]*						X
2256	The IACUC inspection team confirmed that appropriate intraoperative monitoring of anesthetic depth and physiological parameters is performed and documented by personnel. *[Guide (p. 119)]*						X
2257	The IACUC inspection team confirmed that postoperative monitoring and care of appropriate intensity and frequency (includes anesthesia recovery, pain management, management of physiologic needs, assessment of overall well-being, wound healing, suture removal, etc.) was provided and documented by trained personnel. *[Guide (p. 119-120)]*						X
	C. Pain, Distress, Analgesia and Anesthesia						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2300‡	Drug storage and control practices comply with federal regulations for human and veterinary drugs *[Guide (p. 115)]*		X				

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2301‡	Analgesics and anesthetics (as well as other drugs) are used within their expiration date. *[Guide (p. 122)]*		X				
2302	Procedures for acquiring, using and storing anesthetics and analgesics are compliant with legal and safety standards. *[Guide (p. 115; 122)]*		X				
2303‡	Observation and/or record review indicates that before surgery begins, personnel ensured a surgical plane of anesthesia is attained. *[Guide (p. 122)]*						X
2304	The IACUC inspection team determined that neuromuscular blocking agents are used in a humane and appropriate manner in accordance with the IACUC approved protocol. (*[Guide (p. 122-123)]*	X					
	D. Euthanasia						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2350	Personnel are competent in performing euthanasia methods that are appropriate to the animal's age and species and are consistent with AVMA Guidelines. Alternate methods of euthanasia, if used, are approved by the IACUC. *[Guide (p. 124); 9 CFR (2.31(d)(1)(xi))]*		X				
2351‡	Personnel confirm animal death after the euthanasia procedure. *[Guide (p.124)]*		X				
	E. Other Observations						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2400							

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VA SEMIANNUAL EVALUATION of the INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES

Part 2 -- Table of Deficiencies and Departures

This form is for documenting the details about the observations noted in the checklists (Part 1, Sections A and B). Each deficiency, minor or significant, must be entered according to Instructions 2 and 3, below. Each "approved departure", as defined by OLAW, must be entered according to Instruction 4, below. The IACUC may also document on this form, at its discretion, other observations that are not deficiencies, and details about "deviations" that are not "departures", as defined by OLAW – these may be useful in addressing concerns raised by accreditation or regulatory agencies, or for monitoring purposes.

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: The "Date of Last Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities were last completed. Federal regulations require that a new evaluation be completed no later than 6 months after the last evaluation.)
   Double click in the document area to return to the main body of Form 1.

2) Enter deficiencies with corrections that were still pending on the last report. Copy onto this form each item that was reported on Form 2 of the last semiannual evaluation, for which the correction was not yet completed when the last report was signed:
   Enter the date the deficiency was first noted in a semiannual evaluation.
   If the IACUC determines that a change in the scheduled date of correction is appropriate, ~~strike out the previously approved date and~~ add the new date below it.
   Enter the actual date when the correction of the deficiency was completed. If the work is not yet complete, leave the "Actual date of completion" blank, but include in the description any relevant information about progress to date.

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Note: USDA requires the IACUC to report any failure to adhere to the plan and schedule for correction that results in a significant deficiency remaining uncorrected beyond the correction date set by the IACUC. The report must be submitted in writing within 15 business days of missing the correction date set by the IACUC, through the IO, to the Animal and Plant Health Inspection Service (APHIS) and any Federal agency funding the activity involved. Therefore, for the IACUC to change the correction date of a significant deficiency, it must review the justification for the change and approve a new correction date at a convened committee meeting prior to the original correction date.

3) Enter each new deficiency noted on Form 1 (Checklist), Parts A and B, of this report:
The date the deficiency was first noted.
The Part (A or B) and Item # on Form 1 to which it applies.
When applicable, indicate the location where the deficiency was noted.
A description of the specific deficiency -- Include sufficient detail for an outside observer to recognize when it has been corrected), a description of any underlying programmatic or systemic conditions that may have led to the deficiency, and a description of the plans both for correcting the deficiency and for addressing underlying factors so as to prevent recurrence. *[PHS (IV.B.3)]* Be sure to include the name of the individual who will be responsible for overseeing progress on the corrective action, on behalf of the IACUC. (The table will expand to accommodate the text entered.)
The severity of the deficiency (Minor [M] or Significant [S]), as indicated on Form 1.
The scheduled date of correction – enter the date by which the IACUC has determined that the correction should be completed.
The actual date when the correction of the deficiency was completed (leave blank if the work is not yet complete.)

4) Enter each "departure" from PHS Policy, including the provisions of the *Guide*, that has been approved by the IACUC. *[PHS (IV.B.3)]*

For any deviation from a general standard described in the *Guide*, the following series of test questions may be applied to determine whether the deviation is considered a "departure" by OLAW:

1. Does the Guide describe the general standard as a "May" standard? If so, this deviation from the general standard is NOT a "departure". Otherwise, for any "Should" or "Must" standard, proceed to the next question.

2. Does the Guide include an explicitly stated exception that allows for the deviation? If so, this deviation from the general standard is NOT a "departure. Otherwise, proceed to the next question.

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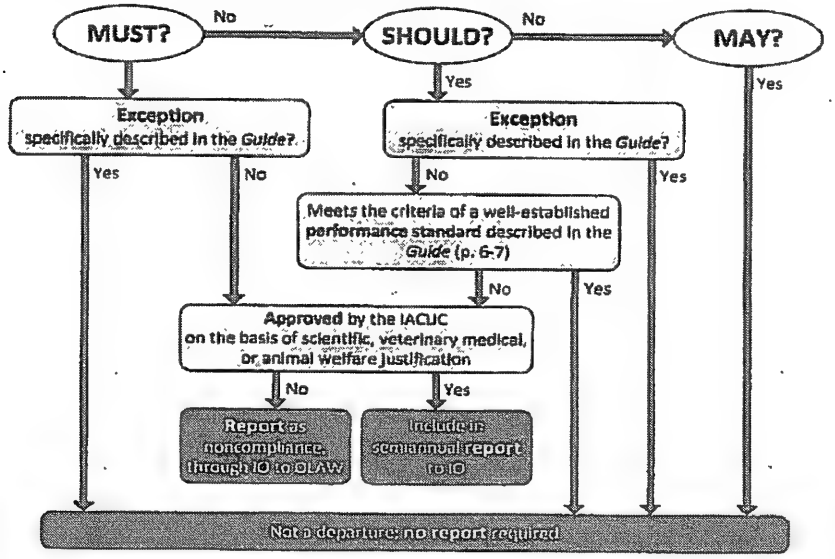
3. Does the deviation meet a well-established performance standard for a "Should" standard, according to locally-defined and continuously monitored performance measures? If so, this deviation from the general standard is NOT a "departure". Otherwise, it IS a "departure", and may be approved by the IACUC only if justified on scientific, veterinary medical, or animal welfare grounds.

The test questions above are summarized in the following flow chart:



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For approved departures that are documented in Appendix 9 of an IACUC-approved ACORP, simply attach a copy of Appendix 9. (The Official Date of Approval in the header must be included, but be sure to redact the name of the PI and the protocol number assigned by the IACUC.) Enter below the table here the total number of Appendix 9 pages attached.

For approved departures that are not documented in an Appendix 9, enter the information into this form as follows:
For "Original Date Noted", enter the date of the IACUC meeting at which the departure was reviewed and approved.
[1300.07.(8,f(1)(ii)2.3); PHS (IV.B.3) ,9 CFR (2.31.(c.)(3)); and Guide (p. 9]
If the departure relates to a specific item on Form 1, enter the Part (A or B) and Item # to which it applies.
If applicable, indicate the location to which the departure applies.
A description of the departure – include a summary of the grounds for granting approval for the departure.
Mark the "D" category, to indicate that the item details a departure.
Enter "N/A" in the columns for the "Scheduled Date of Correction" and the "Actual Date of Correction".

5) Press "Tab" in bottom right cell to add rows to the table.

Original Date Noted	Form 1 Part	Form 1 Item #	Location	Descriptive Details	Category M	Category S	Category D	Scheduled Date of Correction	Actual Date Of Correction
June 14, 2018			(b)(6)	Remove inoperable manometer (b)(6) ▶ Person responsible for overseeing correction:	X			July 27, 2018	June 18, 2018
June 14, 2018				Bio-Bubble Hood not certified Hood taken out of circulation ▶ Person responsible for overseeing correction:	X			June 29, 2018	June 15, 2018
June 14, 2018	1	1754		Burned out light bulb (b)(6) ▶ Person responsible for overseeing correction:	X			July 27, 2018	June 15, 2018
June 14, 2018	1	1351		Cracked floor (b)(6) ▶ Person responsible for overseeing correction:	X			July 27, 2018	July 16, 2018

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June 14, 2018	1	1754	(b)(6)	Burned out light bulb (b)(6) ▶ Person responsible for overseeing correction:	X			July 27, 2018	June 15, 2018
June 14, 2018	1	1353		Replace ceiling tile (b)(6) ▶ Person responsible for overseeing correction:	X			July 27, 2018	
June 14, 2018				Instructions for anesthesia machine ▶ Person responsible for overseeing correction:	X			June 29, 2018	June 22, 2018
June 14, 2018				Bio-Bubble Hood not certified Hood taken out of circulation ▶ Person responsible for overseeing correction:	X			June 29, 2018	June 15, 2018
June 14, 2018	1	1754		Reefer, burned out light bulb (b)(6) ▶ Person responsible for overseeing correction:	X			June 29, 2018	June 15, 2018
June 14, 2018	1	1256		Cleaning container not labeled Labeled container ▶ Person responsible for overseeing correction:	X			June 29, 2018	June 15, 2018
June 14, 2018			(b)(6)	Animal Cages overcrowded Cages weaned ▶ Person responsible for overseeing correction:	X			June 14, 2018	June 14, 2018
June 14, 2018				Emergency Contact sign illegible Replaced sign ▶ Person responsible for overseeing correction:	X			June 29, 2018	June 15, 2018
June 14, 2018				RO Water filters need replacing Replaced filters ▶ Person responsible for overseeing correction:	X			June 29, 2018	June 15, 2018

▶ Total number of Appendix 9 pages attached: 0

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE
PROGRAM AND FACILITIES

Part 3 – Post-Review Documentation

Instructions (The "▶" symbols indicate required information):

1) Enter identifying information in the header above:
Double click in the header area.
Then enter text after each ":"
(Note: The "Date of Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities are completed.)
Double click in the document area to return to the main body of Form 1.

2) ▶Enter the date of the most recent previous Semiannual Evaluation: December 6, 2017

3) Enter the names of all voting members of the IACUC, and identify the member who fills each required role on the committee, in the table in Section D, below. If any alternate members have been appointed, enter the name of each alternate member in the square brackets (e.g., "[Alt: John Smith]") below the name of each primary member for whom the alternate may serve. Only one member, the primary or the designated alternate, should sign in any one row of the table. (Press "Tab" in bottom right cell to add rows to the table.)

4) Complete Sections A-F, below.

A. SUMMARY OF SEMIANNUAL EVALUATION. Summarize the results of this semiannual evaluation, including an analysis of the implications of the results for the animal research program as a whole. The summary should:

- Note the total number of "departures" from PHS policy, including the provisions of the *Guide*, that have been approved by the IACUC.
- Provide summary overviews of the programmatic and facility deficiencies
  - If there were no deficiencies, include a statement to this effect in the report.
  - If deficiencies were identified, evaluate the overall number and severity of the deficiencies, and what the number and severity indicate about the quality of the program and facilities (refer to the complete list provided in Part 2 – Table of Deficiencies and Departures).
- Comment on any patterns or trends suggested by the observations during this semiannual evaluation and also in the light of previous semiannual reports.

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- Acknowledge any laudable aspects of the overall animal care and use program (i.e., related to the program, facility, or personnel).

- Provide a concluding paragraph that: (1) assesses the institution's overall compliance with applicable PHS Policy, the *Guide*, the AWA, and VA Policy; (2) provides recommendations to the IO; and (3) highlights any other pertinent information the IO should be made aware of.

B. DOCUMENTATION of MINORITY OPINION(S). *Any participant in the semiannual evaluation who wishes to provide a minority opinion MUST be allowed to do so [1200.07 (8 f(1)(d)(2)); PHS (IV.E.1.d); 9 CFR (2.31(c)(3))].* Did any participant submit a minority opinion?

_____ Yes ____X___ No If "yes", fill out section E below.

C. Statement of AAALAC Accreditation *[PHS (IV.B.3)].* Are all VA animals housed or used only in facilities that are part of an AAALAC accredited program?

__X__ Yes. If yes, describe the accreditation as indicated below.

Identify the AAALAC accredited program: South Texas Veteran Health Care System

Give the date of the most recent achievement of Full Accreditation: June 14, 2016

____ No. If no, describe the components that are not Fully Accredited, as indicated below.

If VA animals are housed or used at an affiliate institution that is not AAALAC accredited,

Identify the affiliate:

Give the date on which the CVMO approved this arrangement:

If VA animals are housed or used at an institution where the AAALAC accreditation status is other than Full Accreditation,

Identify the institution:

Give the current accreditation status:

Describe briefly the current status of the institution in the process of regaining full accreditation:

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D. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS. *A majority of all voting members (not merely a majority of a quorum) must approve and sign the report [1200.07 (8,f(1)(e)); 9 CFR (2.31(c)(3))]. The report must be completed within one month of the date of the semiannual evaluation to facilitate timely progress on any corrective actions required.*

The undersigned verify that we
1) have reviewed and approved Forms 1 (Checklist, Parts A and B) and 2 (Table of Deficiencies and Departures),
2) have read any minority opinions appearing in item E of this report, and
3) hereby authorize IACUC representatives to review this report with the Medical Center Director:

TYPED NAME	ROLE ON IACUC	SIGNATURE	DATE
(b)(6)	(b)(6)	(b)(6)	7/11/2018
(b)(6)		(b)(6)	7/11/2018
(b)(6)		(b)(6)	7/11/2018

E. MINORITY OPINION(S). If part B is checked "yes", provide the typed minority opinion(s) here:

F. COMMUNICATION WITH DIRECTOR OF THE FACILITY. After a majority of all voting IACUC members approve the report and indicate their approval (in Section D, above) by signatures next to their typed names and roles on the committee, *the report must be discussed personally with the facility Director by at least one voting member of the IACUC, representing the committee. It is recommended that the Attending Veterinarian and the IACUC Chair meet with the Director (any voting member of the IACUC who wishes to participate must be allowed to do so). It is a best practice for the ACOS for R&D and/or the AO for R&D to attend as well. After the meeting, the Director must sign the reporting indicating that he/she has reviewed it. [1200.7(8,f(1)(e))].* **Note: the Director's signature only indicates awareness of the contents of the report, and does not imply agreement with the report or satisfaction with the corrective measures proposed. The report may not be altered after it has been signed by a majority of the voting IACUC membership, but any disputed items may be discussed in a cover memo.**

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Certification: By my signature, I acknowledge receipt of this report, and verify that I have personally discussed its contents with the representatives of the IACUC.

Typed Name of Director	Signature	Date
(b)(6)	(b)(6)	JUL 23 2018

G. FINAL PROCESSING

A signed copy of the complete report (including Parts 1, 2, and 3) must be sent through the ACOS/R&D and Medical Center Director to the CVMO within 60 days of the date of approval and signature by a majority of the voting IACUC members. The R&D Committee should review the approved report as an item of business, but R&D approval is not required before submission of the final document to the CVMO. Send a copy including all signatures as a hard copy to Dr. (b)(6) (b)(6) (b)(6) GA 30033, or as an email attachment to (b)(6) va.gov and (b)(6) @va.gov . The original must be retained for at least three years.

▶Name of VA Facility: South Texas Veterans Health Care System Version 02/28/13
▶Station Number: 671
▶City, State: San Antonio, Texas
▶Date of Semiannual Evaluation: December 11, 2018

VA SEMIANNUAL EVALUATION of the INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES

Part 1 – Checklist

Section A. Review of the Program

The Review of the Program is largely an administrative evaluation of all of the policies, plans, standard procedures, and systems under which the institution fulfills its responsibilities to ensure humane animal care and use. Some of the programmatic items may appear similar to items included in Section B (Inspection of the Facilities), but the focus here (Review of the Program) is on what is intended or expected, while Section B focuses on observed implementation.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted:

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee",
"1200.07" refers to the "VHA Handbook 1200.07, Use of Animals in Research",
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
   (Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]* be completed every 6 months. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
   Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "▶" symbols indicate required information:

▶Date(s) of the most recent previous Review of the Program: June 14, 2018
▶Date(s) on which this Review of the Program was conducted: December 11, 2018

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▶Date of Semiannual Evaluation: December 11, 2018

Names of voting IACUC members who participated in the Program Review:
(The Program Review team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b)(6) [redacted]	(b)(6)	12/11/18
(b)(6)		12/11/18
(b)(6)		12/11/18
(b)(6)		12/11/18

Non-IACUC members who participated in the Program Review:

Name	Title	Date(s) of Participation
(b)(6) [redacted]	(b)(6)	12/11/18
(b)(6)		12/11/18

3) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (Approved by [redacted])
Minor Deficiency
Significant Deficiency

4) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section A), provide details in Part 2 of this form.

5) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

‡ denotes a new "must" item
† denotes a new "should" item

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I. Institutional Policies and Responsibilities

A. Shared Responsibilities						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
100†	A formal written MOU, contract, or agreement is in place for any arrangement in which the VA shares responsibility for animal research with any other institution. This includes the use of an external IACUC and any collaborative arrangements for support, housing, or use of animals in research. *[1200.07 (8.b(1)); Guide, p. 15]* ▶Name(s) of other institution(s) and the date(s) on which current formal written understanding(s) took effect: UTHSA, 2/25/2011		X			
B. General IACUC Function						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
150	The official appointment of each member of the IACUC by the CEO *[PHS (IV.A.3a); 9 CFR (2.31(a))]* is documented and specifies the duration of the appointment and any specific role to which the member is appointed. *[1200.07 (8.a)]*		X			
151	The IACUC has at least five members, including at least one member qualified for and appointed to each of the required roles. *[PHS (IV.A.3); Guide (p. 24)]*		X			
152‡	The IACUC meets as necessary to fulfill responsibilities. *[Guide (p.25)]*		X			
153	The IACUC has adequate authority, administrative support, and other resources to fulfill its responsibilities. *[Guide (p. 14-15)]*		X			
154†	The IO has authority to allocate needed resources. *[Guide (p.13)]*		X			
155	The IACUC communicates regularly with the R&D Committee, by providing the R&D Committee with a set of final, signed, IACUC minutes, and all other notifications required by the R&D Committee, and through an individual who regularly attends meetings of both the IACUC and the R&D Committee. *[1200.07 (8.h (2)); 1200.01 (11.f)]*		X			
156†	Program needs are regularly communicated to the IO by the AV and/or the IACUC. *[Guide (p. 13)]*		X			
157	The IACUC communicates effectively as needed with the SRS and/or the IBC. *[1200.07 (Appendix C-8.a)]*		X			
158	All minority opinions that are submitted are included in the final document that results from any action of the IACUC (e.g., meeting minutes, report of semiannual evaluation, and reports to oversight entities). *[PHS (IV.B.); 9 CFR (2.31(c)(3))]*		X			
159	The research office provides packets to IACUC members no later than 3 business days before the IACUC meeting. This packet must include an agenda with all business items listed, including reviewer assignments for all new protocols. *[1200.07(8.f(2)(d))]*		X			

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160	A written draft of the minutes of the latest IACUC meeting is provided to all IACUC members at least 1 week before the next meeting.		X			
161	Review and approval by the IACUC is required before any work related to the use of animal subjects in VA research begins or is changed significantly. *[1200.07(8)(2));PHS (IV.B.6-7); 9CFR (2.31(c)(6-7)); Guide (p. 26)]*		X			
162	All protocol forms used comply with PHS Policy and USDA AWAR. *[PHS(IV.C);9 CFR (2.31(d)]*		X			
163	The current version of the VA ACORP (or an alternate form that has been approved by the CVMO) is used for any protocol involving work to be supported with VA funding. *[1200.07 (8.f(2)(e))]*		X			
164‡	Consultation with a qualified laboratory animal veterinarian is required before a protocol may be submitted for review by the IACUC. Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol.*[1200.07 (Appendix D - 1.k(2)); 9 CFR (2.31(d)(1)(iv)(B);. Guide (p.5)]*		X			
165‡	No IACUC member participates in the review or approval of any protocol in which that member has a real or apparent conflict of interest (financial or otherwise). *[Guide (p. 26)]*		X			
166	The IACUC does not approve any protocol that involves use of hazardous agents until the Biosafety Official and/or the Radiation Safety Official, as applicable, has signed in Item Z to confirm that the hazardous agents are properly documented in the ACORP. *[1200.07 (Appendix C-.8.e(1)); Guide (p. 21)]*		X			
167	Use of any patient care area for VA-funded animal research is prohibited unless the IACUC and appropriate local clinical and administrative officials first grant approval and the IACUC has reviewed and approved a completed ACORP Appendix 7 that justifies no reasonable alternative to the use of human clinical areas or equipment exists. *[1200.07 (7.k(1))]*	X				
168†	A system of post-approval monitoring is in place to ensure that all work with research animals is performed according to IACUC approved protocols. *[Guide (p. 33)]*				X	
169	The IACUC conducts continuing reviews of all protocols annually. *[9 CFR (2.31(d)(5)]*		X			
170	IACUC approval of each protocol expires on or before the third anniversary of its initial approval. *De novo* review and approval of a complete updated protocol by the IACUC before the date of expiration is required for work on the protocol to continue beyond three years without interruption. *[PHS (IV.C.5)]*		X			
171	Humane endpoints are established for studies in which pain and/or distress is anticipated (i.e., tumors, infectious disease, vaccine challenges, trauma, etc.) *[Guide (p.27)]*		X			
172	The IACUC has established oversight procedures for pilot and field/wildlife studies; studies involving genetically modified animals, food/fluid restriction, and the use of pharmaceutical versus non-pharmaceutical grade chemicals receive special consideration by the IACUC. *[Guide (p. 27-33)]*	X				

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173	Surgical procedures are determined to be major or minor, multiple surgical procedures on a single animal are justified and the outcome evaluated, and multiple survival procedures regardless of species conform to regulated species standards. *[Guide (p.30)]*		X			
174‡	Requests for exemptions from major survival procedure restrictions are made to the USDA/APHIS through the IO. *[Guide (p. 30)]*	X				
175	Toe-clipping is approved by the IACUC only when no other individual identification method is feasible; the procedure is performed aseptically and with pain relief. *[Guide (p.75)]*		X			
176‡	The use of restraint devices is justified in the animal use protocols. IACUC approval is given when the purpose and duration of the restraint are justified. The justification addresses: the lack of feasible alternatives to physical restraint, provisions for the removal of maladaptive animals, training of animals, and appropriate observation of restrained animals. Veterinary care is provided if lesions or illness associated with restraint occur. *[Guide (p 29-30]*		X			
C. Semiannual Evaluations of the Animal Care and Use Program						
		Not Applicable	**Acceptable**	**Approved Departure**	**Minor Deficiency**	**Significant Deficiency**
200	Program Review -- At least every six months, the IACUC reviews the animal care and use program. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B.1); 9CFR (2.31(c)(1))]*		X			
201	Facilities Inspection -- At least every six months, the IACUC inspects all facilities in which animals in the VA animal research program are used. For VA animals used at an affiliate institution, this is done according to the MOU in place between the VA facility and the affiliate. *[1200.07 (8.f(1)); PHS (IV.B); 9CFR (2.31(c)(2))]*		X			
202	Under no circumstances is the report of any semiannual evaluation altered after it has been signed by the IACUC. *[1200.07 (8.f (1)(f))]*		X			
203	The report of each semiannual evaluation of the animal care and use program, signed by the IACUC, is discussed personally with the Director of the VA facility in a meeting with at least one representative voting member of the IACUC. *[1200.07 (8.f(1)(e)); PHS (IV.B); 9 CFR (2.31(c)(5); Guide (p. 25)]*		X			
204	Within 60 days of approval by the IACUC, the report of each semiannual evaluation, signed by the facility Director, is submitted to the CVMO (ORD), or the CVMO's office is notified of the reason for delay and the expected date of submission. *[1200.07(8.k(3))]*		X			

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D. Standard Operating Procedures (SOPs)						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
250	At least annually, the IACUC oversees a review of the complete set of all local SOPs by the Attending Veterinarian with the VMU supervisor and other qualified personnel. *[1200.07 (7.c)]* ▶ Date of latest review: **January 2018**		X			
E. Addressing Concerns about Animal Welfare						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
300‡	The responsibility for animal well-being is assumed by all members of the program; therefore, procedures are in place for the IACUC to receive, review, investigate, and address internal or external concerns or allegations about animal care and use. *[PHS (IV.B); 9 CFR (2.31(c)(4)); Guide (p. 1;23-24)]*		X			
301	Procedures are in place to protect "Whistle-blowers" from discrimination or reprisal for reporting potential regulatory violations within the animal care and use program. *[9CFR (2.32(c)(4)); Guide (p. 24)]*		X			
302	Any animal activity may be suspended by the IACUC (by a majority vote of a quorum), or immediately and unilaterally by the facility Director or any other official designated by the facility Director. *[1200.07 (8.)j; 9 CFR (2 31(c)(8) and 2.31(d)(6))]*		X			
303	The IACUC notifies local administrators (facility Director, RCO, ACOS/R&D) and external oversight entities (CVMO, ORO, OLAW, and AAALAC) immediately when an investigation is undertaken. *[1200.07 (8.i)]*		X			
304	Within 5 business days of determining that a reportable deficiency has occurred, the IACUC submits an initial report to the facility Director and the IO, with copies to the ACOS/R&D and other relevant research review subcommittees. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
305	Within 5 business days (*ORO requirement*) of receiving a report of a reportable deficiency from the IACUC, the facility Director and IO submit the report to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1058.01(8.e); PHS (IV.F.3); 9 CFR (2.31(c)(3) and 2.31(d)(7))]*		X			
306	The corrective action plan, the timetable for its implementation, and interim and final reports on the correction of each reported deficiency are submitted to the facility Director and IO, and through them to the CVMO, ORO, OLAW, AAALAC, the Animal Care Section of USDA APHIS, and any other non-VA funding sources, as applicable, with copies to the IACUCs of any affiliate institutions with shared responsibility. *[1200.07 (8.i)]*		X			

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F. Reporting to Oversight Entities						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
350	The USDA Annual Report of Research Facility was completed and submitted by December 1 within the past year, as required by USDA, and a copy is on file locally. *[9CFR (2.36)]* ▶ Date of most recent submission: **11/30/2018**		X			
351	The VA facility is covered by a PHS Assurance, approved by OLAW, and revised as needed to reflect any significant changes in the animal care and use program. *[PHS (IV.A)]* ▶ Name of the Institution that holds the PHS Assurance: **STVHCS** ▶ Effective date of most recent approved Assurance: **1/29/2018**		X			
352	The annual report to OLAW was submitted within the past year by the end of the month immediately following the end of the last reporting period, and a copy is on file locally. *[PHS (IV.F.1-2)]* ▶ Date of most recent submission: **1/2018**		X			
353	The VA facility is fully accredited by AAALAC, and a copy of the triennial comprehensive AAALAC Program Description is on file locally. *[1200.07 (7.c)]* ▶ Name of the Institution that holds the accreditation: **STVHCS/VMU**		X			
354	The AAALAC Annual Report was submitted within the past year as required by AAALAC, and a copy is on file locally. *[1200 07 (8.f(2)(b))]* ▶ Date of most recent submission: **1/9/2018**		X			
355	The VA Veterinary Medical Unit (b)(6) annual report, which includes mice and rats, was submitted online by the specified deadline (usually January 15) within the past year. *[1200 07 (8.f(4))]*		X			
356	All other correspondence with oversight entities (USDA, OLAW, AAALAC, and ORO) relevant to the animal research program (except for routine notifications and reminders) is copied to the CVMO within 15 days of receipt or submission. *[1200.07 (9)]*		X			
357	All documents relevant to the animal care and use program are maintained on file for at least three years, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. This includes acquisition/disposition records, IACUC meeting minutes, semiannual reports, and all reports to, and correspondence with, oversight entities. *[1200 07 (Appendix E-2. c); 9CFR2 35(f); PHS (IV.E)]*		X			
358	All documents relevant to individual studies are maintained for at least the duration of the study and for three additional years after the completion of the study, or according to the latest VA requirements (current VA policy requires all records to be kept indefinitely), whichever is longer. *[1200.07 (8.f(1)(h));9CFR2.35(f); PHS (IV.E)]*		X			

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G. Personnel Qualifications and Training						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
400‡	The IACUC does not approve any protocol until each individual listed on the protocol has documented completion of required VA training at the prescribed intervals. *[1200.07 (8.m(1)).; PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 15); US Government Principle VIII)]*		X			
401‡	The IACUC confirms that each individual is appropriately trained before approving that individual to perform the procedure without supervision. This includes non-surgical and surgical procedures, anesthesia monitoring, and euthanasia. *[PHS (IV.C.1.f); 9 CFR (2.31(d)(1)(viii); Guide (p. 15 & 115)]*		X			
402‡	All personnel are documented as being appropriately trained for their positions, and participating in formal and/or on-the-job continuing education at the prescribed intervals. *[1200.07 (8.m); PHS (IV.A.1.g); 9 CFR (2.32); Guide (p. 16-17)]*		X			
403†	IACUC members receive training in all aspects of humane animal care and use through the documented completion of VA training at the required intervals. *[PHS (IV.A.1.g); 9 CFR (2.32); 1200.07 (8.m); Guide (p.17)]*		X			
H. Occupational Health and Safety						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Occupational Health and Safety Program (OHSP)						
450‡	An OHSP has been established and is maintained by the VA facility to protect personnel involved in animal research (laboratory or field setting) from associated risks including but not limited to direct animal contact, exposure to unfixed tissues or fluids, hazardous agents used in the research, etc. *[PHS (IV.A.1.f); Guide (p.17; 32); 1200.07 (10)]*		X			
451	All personnel at risk of exposure have the opportunity to participate in the OHSP. This includes personnel whose duties include work with animals (e.g., VMU staff, investigators, research technicians), regardless of whether they are paid employees, without compensation (WOC) personnel, students, or trainees, as well as , personnel that do not have contact but are exposed to animals (e.g., maintenance and engineering staff assigned to the VMU, other service personnel, etc.). *[1200.07 (10.a); Guide (p. 18)]*		X			
452	**Hazard Identification and Risk Assessment** – The IACUC, the local veterinarians, the SRS, and the Safety Officer work together effectively to identify potential hazards that exist in the animal research program, to assess the consequent risks to personnel, and to determine appropriate strategies to manage the risks. *[Guide (p. 18-19)]*		X			

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453	**OHSP Training** – Training is provided to all personnel covered by the OHSP, with regard to personal hygiene practices, use of safety equipment, and SOPs appropriate to each individual's duties and risks of exposure. *[Guide (p. 20)]*		X			
The OHSP – Facilities and Procedures						
454	**Ergonomic efficiency** – Procedures and policies are in place to reduce the risks of ergonomic injuries to personnel (e.g. facility design, SOPs, and the use of equipment such as ramps, carts, and hydraulic lifts). *[Guide (p.19- 20)]*		X			
455	**Control of exposure** – Personal exposure to hazardous agents is limited through the design of the facility, establishment of SOPs (e.g. separation of animals treated with hazardous agents from untreated animals), selection/maintenance/certification of safety equipment (e.g., showers, eyewash stations, fume hoods, etc.), and careful monitoring of agents to ensure that they remain within permissible ranges. *[Guide (p. 19-20)]*		X			
456	**Policies and Procedures associated with nonhuman primates (NHPs)** – have been established and include training with regard to the risks of exposure to *Macacine herpesvirus 1* (formerly *C. herpesvirus* or Herpes B virus); tuberculosis screening for exposed personnel; training on and the handling of bites, scratches, or other injuries; medical evaluation and treatment of injuries; and provision of appropriate PPE. *[Guide (p. 23)]*	X				
The OSHP – Personal Hygiene						
457	The OHSP includes guidelines on appropriate personal hygiene practices, including hand washing and showering, use of protective clothing, and restricting consumption of food and beverages to designated break areas. *[Guide (p. 20-21)]*		X			
458	The VA facility provides uniforms, laundry service, and all other necessary personal protective equipment (e.g., gloves, ear protection, protective eyewear, steel-toed footwear, respirators, with appropriate fit testing and training, and other special equipment), as appropriate to the duties of the personnel. *[Guide (p. 20-22)]*		X			
The OHSP – Medical Evaluation and Preventive Medicine for Personnel						
459	A pre-employment medical evaluation is performed on each prospective new employee. *[1200.07(Appendix C-4(2)(a))]*		X			
460	A follow-up medical evaluation is performed at routine intervals (usually annually) on each OHSP participant. *[1200.07(Appendix C-4(2)(b))]*		X			
461	Enrollment in OHSP is prerequisite to approval for access to the [b)(7)(E)] and for beginning work with animals. *[1200.07(Appendix C-4(2)(c))]*		X			
462	Personnel are not permitted to decline immunizations or tests required by the VA facility that are necessary to protect the health of the animals or personnel. *[1200.07 (10.b)]*		X			
463	All vaccines (e.g., tetanus, rabies) are provided to personnel as currently recommended by CDC, free of charge. *[1200.07 (10.f(2)); Guide (p. 23)]*		X			

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464	Personnel are required to report and be treated for all injuries and illnesses potentially related to working in the VMU or other animal research areas, or otherwise in connection with work with animals. *[1200.07(Appendix C-4.b; Guide (p. 23)]*		X			
465‡	The program considers confidentiality and other legal factors as required by federal, state and local regulations. *[Guide (p. 22)]*		X			
466‡	If serum samples are collected, the purpose is consistent with federal and state laws. *[Guide (p. 22)]*	X				

II. Physical Plant

A. General						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
500	The physical plant infrastructure (includes HVAC, plumbing, lighting, power, control systems, etc.) is adequate to support the needs and performance standards of the animal care and use program, and is compliant with and meets all applicable building codes *[Guide (p. 133-136)]*		X			
501	Policies and procedures are in place to ensure that facilities and equipment are properly maintained and functional. *[Guide (p. 133-136)]*		X			

III. Operations Related to Animal Environment, Housing, and Management

A. Physical Environment						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
Temperature, Humidity, and Ventilation						
550	The response of facilities management (FM) personnel to elevations in temperature in animal rooms is tested and reported to the IACUC at least annually, and the response by FM personnel is satisfactory. *[1200.07 (7.a(2)(c))].* ▶Date of latest test: **12/14/2018**		X			
551	HVAC reheat units serving animal rooms are designed so as to fail in the "off" position, preventing over-heating of animals. *[1200.07 (7.a(2)(a))]*		X			
Noise						
522	Policies are in place to minimize exposure of the animals and personnel to excessive vibration, unnecessary sounds, and any sounds louder than 85dB. *[Guide (p.49-50)]*		X			

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B. Husbandry		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
General						
600‡	Oversight of daily husbandry and other animal care duties has been assigned to a single individual (usually, the VMU Supervisor) when a full-time veterinarian is not available on site. *[Guide (p. 14)]*		X			
Population Management						
601	Methods of animal identification have been established, which provide the protocol number and other pertinent information. Where applicable, genotype information is provided using accurate, consistent, and unambiguous genotype nomenclature. *[Guide (p. 75-77)]*		X			
Behavioral Management						
602	**Activity** – Each animal must have opportunities to engage in activity (motor, cognitive, and social) appropriate to its species. *[Guide (p. 60;63)]*		X			
603	**Social Environment** – Animals must be housed in appropriate compatible social groups or when single housing of social species is required (by an approved protocol or because of veterinary concerns) have contact with compatible conspecifics and/or enrichment. *[Guide (p.51, 63-65)]*		X			
604	**Environmental Enrichment** – The program to enrich the structural environment of each animal (structural additions, exercise, manipulative activities, and cognitive challenges) to accommodate the expression of species-typical postures and behavior is reviewed regularly by the IACUC, researchers, and veterinarians. *[Guide (p. 52-54)]*		X			

C. Animal Procurement and Transportation		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
650‡	Only animals that are obtained lawfully may be used in VA research. *[1200.07(7.b(1)); Guide (p.106)]*		X			
651	Animal procurement is approved and initiated only after confirmation that: (1) the source of animals is appropriate; (2) appropriate housing and care for the animals upon arrival is coordinated with animal care staff; and (3) the animals are designated for use on an IACUC approved protocol. *[Guide (p. 106-109)]*		X			
652‡	Transportation (including intra-institutional, inter-institutional, interstate, international, and from commercial or non-commercial sources) complies with federal and international regulations, as applicable, and is arranged to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[Guide (p. 107); 9 CFR (Part 3, Standards)]*		X			

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D. Preventive Medicine						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
700	The institutional animal care and use program strives to maintain research animal populations that are as free of infectious agents as possible. *[1200.07 (7.d(1))]*		X			
701	A program of veterinary care, overseen by a VMO or VMC, is in place for the surveillance, diagnosis, treatment, and control of non-protocol diseases or conditions (especially those with zoonotic potential, such as Q-fever, LCMV, parasites, etc.), and for the management of diseases or conditions induced by experimental requirements. *[Guide (p. 112-114)]*		X			
702	Quarantine and stabilization of newly received animals, as well as, separation of animals by species, source, health status, and intended use, as appropriate, are used to prevent spread of pathogens. *[Guide (p. 109-112)]*		X			
E. Waste Disposal						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
750	Procedures are in place for sanitation of waste containers, as well as procedures for safe removal and disposal of conventional, biological, and hazardous wastes (including soiled bedding). All waste disposal procedures comply with facility, municipal and federal policies and regulations. *[Guide (p 73-74)]*		X			
F. Pest Control						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
800	A regularly scheduled and documented program of monitoring for and controlling pests has been implemented, which includes measures to prevent vermin entry and harborage. *[Guide (p. 74)]*		X			
801	Animal and human health concerns encourage the use of non-toxic methods of pest control instead of chemical pesticides whenever possible. If chemical pesticides are to be used, the investigators whose animals may be exposed are consulted to ensure that scientific objectives are not unnecessarily compromised. *[Guide (p.74)]*		X			
G. Medical Supplies						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
850	All controlled substances needed for animal research on VA property are ordered and received by the local VA pharmacy, and dispensed to research personnel as needed. *[1200. 07 (7.m)]*		X			

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851	Use of non-pharmaceutical grade compounds, expired drugs or medical supplies (e.g., sutures, antiseptics, etc.) in animals is limited to protocols in which such use has been documented not to jeopardize animal welfare or compromise the validity of the study. *[PHS (FAQ F.4); Guide (p.31)]*		X			
H. Emergency, After Hours, Weekend, and Holiday Animal Care						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
900	Qualified personnel are assigned to provide routine care for the animals on weekends and holidays. *[Guide ((p. 74); 9 CFR (2.33(b))]*		X			
901	Veterinary care is available as needed after regular work hours on weekends, and on holidays; procedures are in place for timely notification of a veterinarian in case emergency care is needed. *[Guide (p. 74); 9 CFR (2.33(b))]*		X			
902‡	A disaster plan that addresses the needs of both personnel and animals is in place including animal euthanasia if necessary; the plan is approved by the IACUC. *[Guide (p. 35;75)]*		X			
903†	The disaster plan addresses triage procedures, emergency/life support services; preservation of irreplaceable animals, essential personnel, and disaster response training. The animal facility plan is approved by institution, is a component of the overall disaster plan, and is provided to first responders. *[Guide (p. 35; 75)]*		X			
904	Key animal facility personnel (e.g., the Attending Veterinarian and the (b)((b)(6) are included among the official responders to be contacted in emergencies that involve animals. *[Guide (p.75)]*		X			

IV. Veterinary Medical Care

A. Role of the Veterinarians						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
950 ‡	A high quality veterinary care program consistent with ethical standards has been established. *[Guide (p. 105)]*		X			
951 ‡	Each VMO and VMC has training and/or experience in lab animal medicine and with the species used. *[Guide (p. 15); 9 CFR (2.33)]*		X			
952†	The VMOs and VMCs provide guidance to research personnel with regard to the humane care and use of the animals in the context of the scientific and regulatory requirements (including appropriate handling of animals, sedation, anesthesia, surgery and peri-operative care, analgesia, and euthanasia). *[Guide pg. 105-106, 113-114; 9 CFR (2.31(d)(1)(iv)(B) and 2.33(b)(4-5))]*		X			

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953	When veterinary care services are provided by a part-time or consulting veterinarian, the veterinarian's visits are of sufficient frequency to meet programmatic needs. A written program of veterinary care for USDA regulated species is in place if a full-time attending veterinarian is not on-site. *[Guide (p. 14);USDA-APHIS Policy #3]*		X			
954 ‡	Veterinary care is available as needed and effective procedures are established for timely reporting of animal injury, illness, or disease and for veterinary assessment, treatment, or euthanasia. The veterinarian is authorized to treat, relieve pain, and/or euthanize. *[Guide ((p. 106, 113, 114, 120, and 122-123); 9 CFR (2.33(b))]*		X			
955 ‡	The Attending Veterinarian has the authority and resources needed, and uses them appropriately to manage all aspects of animal care and use in the animal research program. *[Guide (p. 14); 9 CFR 2.33(a)(2)]*		X			
956 ‡	Veterinary access to all animals is provided. *[Guide (p. 14)]*		X			

B. Surgery

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1000	Aseptic technique is required for all survival surgery; is appropriate to the species; and includes preparation of the patient, surgeon, sterile materials, and supplies, as well as appropriate operative technique to reduce the risk of infection. *[9CFR (2.31(d)(1)(ix); Guide (p.118-119)]*		X			
1001	Procedures are in place to ensure that appropriate surgical anesthesia and analgesia are provided. Postoperative monitoring and care are provided by trained personnel and documented. *[Guide (p. 119-120)*		X			
1002	Major surgical procedures in non-rodents may be performed only in dedicated surgical facilities. *[9CFR (2.31(d)(1)(ix))]*	X				
1003	A system of ongoing and thorough assessment of surgical outcomes is in place to ensure that appropriate procedures are followed and appropriate corrective changes are implemented in a timely manner. *[Guide (p. 115)]*	X				
1004	Pre-surgical planning includes veterinary input and addresses location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping, etc. *[Guide (p.116)]*		X			
1005	For non-survival surgery, the surgical site is clipped, gloves are worn, and the surgical area and instruments are clean. *[Guide (p.118)]*		X			

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C. Pain, Analgesia, and Anesthesia		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1050	Guidelines for the assessment and management of pain, distress, and animal wellbeing have been established, and include monitoring for effectiveness of pain control, consideration of non-pharmacologic pain control methods, and guidance regarding the selection and use of anesthetics and analgesics. *[Guide (p. 121-122)]*		X			
1051 ‡	Procedures are in place to assure anti-nociception before surgery begins. *[Guide, p 122)]*		X			
1052	Special precautions for the use of paralytics are in place to ensure adequate anesthesia. *[Guide (p 123)]*	X				
1053 ‡	The drug storage and control program complies with federal regulations for human and veterinary drugs; procedures have been established to ensure that analgesics and anesthetics are used prior to their expiration date. *[Guide (p.115)]*		X			
1054 †	Anesthetics and analgesics are acquired, stored, and disposed of in a legal and safe manner; drug records and storage procedures are reviewed during facility inspections. *[Guide, p. 115 & 122)]*		X			

D. Euthanasia		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency
1100	The methods of euthanasia approved by the IACUC are consistent with the AVMA recommendations for the species involved. *[Guide (p. 123); PHS (IV.C.1.g); 9 CFR (2.31(d)(1)(i))]*		X			
1101	Personnel receive training on euthanasia methods appropriate for the species and age of the animal to minimize the potential for pain and distress. *[Guide (p. 123-124)]*		X			
1102 ‡	Procedures and training are in place to ensure that death is confirmed. *[Guide (p. 124)]*		X			

V. Animal Care and Use Program Work Orders

Instructions: Enter work order data as prompted for Tables 1 and 2. All work orders related to the animal care and use program should be entered, whether or not they resulted from a semiannual evaluation. Use Table 3 to summarize the work orders in Tables 1 and 2.

Table 1: Work Orders Completed - include all work orders completed since the previous semiannual program evaluation (▶Date(s) of previous evaluation:).

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#	Enter M, S, or No, for Minor or Significant deficiency noted in semiannual evaluation, or Not related to semiannual evaluation	Work order (local reference) number	Summarize work requested	Date work order was submitted	Date work order was completed	Elapsed days from submission to completion
1	Not		Repair water leak	9/14/18	9/14/18	1
2	Not		Replace burned-out lights	9/18/18	9/19/19	1
3	Not		Repair door closure mechanism	10/15/18	10/18/18	3
4	Not		Sand and Seal Doors	10/16/18	10/25/18	9
5						

Table 2: Work Orders Not Yet Completed - include all open work orders generated by previous semi-annual evaluations and other sources. Work orders placed as a result of the current semi-annual review are also entered below.

#	Enter M, S, or No, for Minor or Significant efficiency noted in semiannual evaluation, or Not related to semiannual evaluation	Work order (reference) number	Summarize work requested	Date work order was submitted	Elapsed days from submission until _____ (enter date used to calculate elapsed days)
1					
2					
3					
4					
5					

Table 3: Summary

Table #	Number of work orders entered	Average days elapsed
	4	3.5

Comments (provide any additional information relevant to the numbers of days required for completion of the work orders submitted):

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 1 – Checklist
Section B. Inspection of the Facilities

The Inspection of the Facilities focuses on a physical and visual evaluation of buildings, equipment, and the environment in which animals are maintained and utilized. Some of the items here appear similar to items included in Section A (Review of the Program), but the focus here (Inspection of the Facilities) is on what is actually observed in the animal facilities, while Section A focuses on what is intended or designed.

NOTE: The checklist is designed to prompt review according to regulatory requirements, and focuses on the minimum standards that must be met. The wording in the checklist is not to be interpreted as altering the regulatory requirements in any way, but represents guidance from the office of the CVMO. For specifics about the regulatory requirements and recommended best practices, the references provided in square brackets must be consulted:

"1200.01" refers to the "VHA Handbook 1200.01, Research and Development (R&D) Committee",
"1200.07" refers to the "VA Handbook 1200.07, Use of Animals in Research",
"PHS" refers to the "PHS Policy on Humane Care and Use of Laboratory Animals",
"9 CFR" refers to the "USDA Animal Welfare Act Regulations and Standards, Code of Federal Regulations, Title 9",
"US Govt Principle" refers to the "US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training", and
"Guide" refers to the National Research Council's "Guide for the Care and Use of Laboratory Animals", 8th edition, 2011

Instructions:

1) Enter identifying information in the header above:
Double click in the header area.
Then enter text after each ":"
(Note: Federal regulations require that a new Review of the Program be completed every 6 months *[PHS (IV.B.1); 9 CFR (2.31(c)(1))]*, and a new Inspection of the Facilities be completed every 6 months *[PHS (IV.B.2); 9 CFR (2.31(c)(2))]*. The "Date of Semiannual Evaluation" is the date on which the last of the components of the semiannual evaluation was completed.)
Double click in the document area to return to the main body of the form.

2) Enter the information requested below. The "▶" symbols indicate required information:

▶Date(s) of the most recent previous Inspection of the Facilities: December 6, 2017
▶Date(s) on which this Inspection of the Facilities was conducted: June 14, 2018

Names of voting IACUC members who participated in the Facility Inspection:
(The Facility Inspection team must include a minimum of two voting members of the IACUC [9 CFR (2.31(c)(3))]. Any non-members who also participate, at the discretion of the IACUC, may be listed in the second table.)

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Name	Specific Role on IACUC (if any)	Date(s) of Participation
(b)(6)	(b)(6)	12/11/18
		12/11/18
(b)(6)		12/11/18
(b)(6)		12/11/18

Non-IACUC members who participated in the Facility Inspection:

Name	Title	Date(s) of Participation
(b)(6)	(b)(6)	12/11/18
(b)(6)		12/11/18

3) The IACUC must inspect semiannually all units of the animal care and use program, including the following:
all areas within the VA animal facilities;
all spaces outside the VA animal facilities where animals are housed for > 12 hours;
any areas where any procedure is performed on animals.

Identify each unit subject to inspection (press Tab in bottom right cell to add rows to the table):

Location (name of site, building name and room number, etc.)	**Species**	**Type of Space** (e.g., VMU, satellite, investigator laboratory) **and the Nature of the Procedures Performed** (e.g., housing, terminal surgery, behavioral training, etc.)	**Name and Role** (e.g., VMU Supervisor, PI) **of Responsible Individual**
(b)(6)	Mice/Rats	VMU	VMU Supervisor

4) For each item in the checklist, type "X" in the column that applies (shaded cells should not be used):

Not Applicable
Acceptable
Approved Departure (approved by the IACUC)
Minor Deficiency
Significant Deficiency
Could Not Evaluate (during this inspection)

The last line of each section of the checklist is designated "Other Observations", for documentation of relevant observations that are not directly addressed by the checklist items.

5) For each item marked as an Approved Departure, a Minor Deficiency, or a Significant Deficiency here (Part 1, Section B), provide details in Part 2 of this form.

6) Items that reflect changes in the 8th edition of the *Guide* are flagged as follows, and may require particular attention as the 8th edition is implemented.

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‡denotes a new "must" item
† denotes a new "should" item

I. Implementation of Institutional Policies

	A. Performance of Work According to Protocol	Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1150	Current versions of IACUC approved protocols are readily available to animal care staff as well as research staff.		X				
1151	Animal research procedures (observed by the IACUC inspection team includes but is not limited to conduct of surgery, behavioral testing, training, exercise, administration of anesthetics and analgesics, etc.) are being performed according to the protocols approved by the IACUC. *[PHS (IV.C.1); Guide (p. 33-34)]*		X				
1152	Individuals observed working with animals are identified on the corresponding protocols approved by the IACUC.		X				
1153	Routine husbandry tasks observed are being performed according to documented SOPs.		X				
	B. Addressing Concerns about Animal Welfare	Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1200	Contact information for responsible local and VA Central Office personnel are posted prominently in the animal facility for reporting of animal welfare concerns. *[1200.07 (8.k(2)); Guide (p. 24)]*		X				
	C. Occupational Health and Safety	Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1250	Appropriate hazard signs and relevant safety protocols are posted in plain view, and the MSDSs are readily available, where specific hazardous agents are in use. *[1200.07 (Appendix C-8 h(1)-(2))]*		X				
1251	Wherever gas anesthetics are used, waste anesthetic gas is removed via a scavenging system or by another approved method. *[Guide (p. 21; 145)]*		X				
1252	Labels on safety equipment (e.g. eye wash, emergency shower, fume hoods, etc.) indicate that maintenance and certification are current. *[Guide (p. 20)]*		X				
1253	Good safety practices are evident as indicated by proper glass and sharps disposal, gas cylinders appropriately secured, proper separation of chemicals and wastes, etc. *[Guide (p.74)]*		X				

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1254	Supplies are readily available for treatment of bites, scratches, and puncture wounds according to current CDC recommendations. *[Guide (p. 23)]*		X				
1255	Adequate supplies of appropriate attire and clean protective clothing, including disposable PPE (e.g. gloves masks, shoe covers, etc.) are readily available; soiled items are disposed of, laundered, or decontaminated according to approved facility procedures. *[1200.07(Appendix E-2.e) ;Guide (p. 20-22)]*		X				
1256	The IACUC inspection team determined that with regard to the use of hazardous agents, appropriate procedures, containment equipment, and personal protective equipment are used to safeguard personnel and animal health and are consistent (where applicable) with APHIS, USDA, and CDC Select Agent Regulations and other federal, state, and local regulations including security measures. *[1200.07 (Appendix E-2(i)); Guide (p. 20-22; 148-149)]*		X				
	D. Other observations						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1300							

II. Physical Plant

	A. General						
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1350	Corridors are sufficiently wide and clear of obstacles so that personnel and equipment can move easily without impediment. *[Guide (p. 136)]*		X				
1351	Floor surfaces are moisture-resistant, nonabsorbent, and impact-resistant; floors are in good condition, without cracks, evidence of delamination or deterioration, of appropriate texture, and are clean and sanitized. *[Guide (p. 137-138); 9 CFR (Part 3, Standards)]*		X				
1352	Floors slope appropriately to drains; drains are filled with liquid, and those not in use for long periods are capped/covered. *[Guide (p. 138)]*		X				
1353	Wall and ceiling surfaces are smooth, moisture-resistant, nonabsorbent, impact-resistant, washable, and free of unsealed penetrations. These surfaces were found to be clean, sanitized according schedule, free of defects and evidence of water damage. *[Guide (p. 138-139); 9 CFR (Part 3, Standards)]*		X				

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1354	Doors are adequately sized, fit tightly within their frames, are sealed to prevent vermin entry, and are in good repair; preferred features include self-closing mechanism, sweeps, recessed handles, and protective hardware. *[Guide (p. 137)]* Note: With the exception of doors with viewing windows that are needed for safety and other reasons, windows in animal facilities should generally be avoided.) *[Guide (p. 137)]*		X				
Heating, Ventilation, and Air-Conditioning (HVAC) System							
1355	Maintenance of temperature, humidity, and air pressure differentials within recommended ranges throughout the facility is documented. *[Guide (p. 43-47)]* ▶List the document(s) reviewed: **Daily Health Check Logbook**		X				
1356	HVAC reheat units serving animal rooms fail in the "off" position, as designed, to prevent over-heating of animals. *[1200.07 (7.a(2)(a))]*		X				
1357	Effective back-up mechanisms are in place to maintain temperatures and humidity within acceptable ranges in the event of an electrical outage or failure of the HVAC system in the animal research facility. *[Guide (p. 141)]*		X				
Power & Lighting							
1358	Moisture-resistant switches and outlets, and ground-fault interrupters, have been installed in wet areas (e.g. cage processing, aquatic holding areas, etc.) *[Guide (p. 141)]*		X				
1359	Light fixtures, timers, switches, and outlets are properly sealed to prevent vermin from being harbored in them. *[Guide (p. 141)]*		X				
1360	Protective covers are in place over light bulbs and light fixtures. *[Guide (p. 141)]*		X				
1361	In the event of a power failure, alternative or emergency power supply is available to maintain critical services. *[Guide (p. 141)]*		X				
Noise Control							
1362	Noise reduction practices are utilized. *[Guide (p. 49-50; 142)]* For example: • Entry doors from corridors to animal housing areas are closed when not in use. • Carts, racks, and other equipment are equipped with casters. • Noisy animals are grouped in one section of the animal • facility. • Sound-generating equipment is selected and located to minimize disturbance to animals		X				
1363	Vibration dampening procedures are practiced where applicable. *[Guide (p. 142)]*		X				
Environmental Monitoring							
1364	Environmental conditions in animal holding spaces and other sensitive areas are monitored and verified by one or more mechanism or systems. *[Guide (p. 143)]*		X				

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B. Facilities for Sanitization							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1400	A dedicated cage and equipment processing area of appropriate size and design (including safety features, traffic flow, utilities, egress, HVAC capacity, clean storage, etc.) is available and meets program needs. *[Guide (p. 143)]*		X				
1401	Appropriate safety precautions and equipment are in place and in use; including but not limited to protective clothing and equipment, posting of standard operating procedures and warning signage, eyewash/shower stations, and functioning safety devices to prevent trapping of personnel inside of walk-in equipment (e.g., cage/rack washers, bulk sterilizers). *[Guide (p. 143)]*		X				
1402	Cage wash temperatures and sterilizer effectiveness are monitored and appropriate records are maintained. *[Guide (p. 72-73)]*		X				
C. Storage Areas							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1450	Food and bedding, toxic or hazardous agents, and wastes are stored in separate designated areas. *[Guide (p. 141)]*		X				
1451	Food and bedding is stored in a vermin-free area and is protected from contamination. Temperature and humidity conditions are appropriate in food storage areas. *[Guide (p. 141)]*		X				
1452	Food stuffs/diets are obtained from reputable vendors and are managed to maintain quality *[Guide (p. 65- 67)]*: • Feed bag stocks are rotated and used prior to expiration date or discarded. • Open bags of feed are stored in sealed, vermin-proof containers. • The storage area is clean and orderly; feed bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation.		X				
1453	Bedding bags are stored off the floor on pallets, racks, or by other methods with adequate clearance from the wall to ensure good sanitation. Autoclaved bedding has been allowed to dry before use or storage. *[Guide (p. 69)]*		X				
1454	Refrigerated storage for animal carcasses and tissue waste is at <7°C (44.6 °F). *[Guide (p. 142)]*		X				

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D. Facilities for Aseptic Surgery							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1500	Are located and designed to minimize traffic and/or contamination; the facilities include areas for surgical support, animal preparation, surgeon scrub, operating room and postoperative recovery that separate the related non-surgical activities from the operating room. Equipment and services needed to support the use of the surgery facility are available. *[Guide (p. 144-145)]*		X				
1501	Procedures are in place and have been implemented to assure effective sanitation of the operating room, surgical instruments and equipment, appropriate management and use of stored sterile supplies, scavenging of anesthetic gases, monitoring of drug inventory, and recordkeeping for anesthesia and postoperative care. *[Guide (p. 115; 122; 144-145)]*		X				
1502	Equipment needed to support aseptic surgery (e.g., autoclaves, anesthetic vaporizers, etc.) are in good repair and certifications are current. *[Guide (p. 20)]*		X				
E. Special Facilities *(include barrier, aquatics laboratory study areas, procedure areas, imaging, core service facilities ,etc.)*							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1550	Where applicable, the facility/room has appropriate drug storage/monitoring, sharps disposal, anesthetic monitoring and scavenging, safety equipment/procedures (safety signage, eyewash stations, secured gas cylinders, etc.) and carcass disposal. *[Guide (p.19-21;73-74;115;120;122;134)]*		X				
1551	Specialized facilities have procedures and equipment in place to minimize contamination risk. *[Guide (p. 147-150)]*	X					
1552‡	Appropriate sensors and ventilation are provided for areas where cryogen gases are used or stored. *[Guide (p. 147)]*	X					
1553	Aquatic housing areas feature water impervious surfaces, slip resistant floors, ground-faulted electrical receptacles or circuits, and HVAC capacity to maintain appropriate temperature and humidity control. *[Guide (p 150-151)]*	X					
F. Ancillary Areas							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1600	Showers, sinks, toilets, locker rooms, and break areas are available for personnel and are separate from animal holding or support areas. [*Guide (p. 19; 136)]*		X				
1601	Space for administrative and supervisory personnel, including space for staff training and education are available and separate from animal holding or animal support areas. [*Guide (p 136)]*		X				

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G. Security							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1650	Perimeter doors are closed and locked. *[1200.07 (7.i)]*		X				
1651	Security measures are in practice and mechanisms for controlling entry into the facility function appropriately. *[1200.07 (7.i); 1200.01.9.c; Guide (p. 23;151)]*		X				
H. Other Observations							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1700							

III. Animal Environment, Housing, and Management

A. Physical Environment							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
Temperature, Humidity, and Ventilation							
1750	Temperature and humidity in animal rooms are within acceptable ranges. *Guide (p. 43)]*		X				
1751	Odors, ammonia levels, and drafts are all within acceptable limits; ventilation and air quality are adequate. *[Guide (p. 45)]*		X				
1752	The supply air to animal holding is 100 % outside air treated with appropriate filtration. Note: Exhaust air recycled into HVAC systems serving multiple rooms is a cross contamination risk and generally should be avoided. Exhaust air should be treated with at least 85-95% ASHRAE efficient filters prior to recycling. *[Guide (p. 45-47; 140)]*		X				
Illumination							
1753	Lighting in animal rooms is on appropriate diurnal cycles. *[Guide (p. 47)]*		X				
1754	The intensity, quality, distribution, and rates of change of intensity of the light are appropriate to the species in each room. *[Guide (p. 47-48)]*		X				
Noise							
1755	Radios and other equipment that produce unnecessary sound audible to the animals are not in use in animal rooms, except as required by approved protocols for research or enrichment. Vibration is minimized where possible. *[Guide (p. 49-50)]*		X				

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B. Husbandry								
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
General								
1800	Animals are appropriately separated by species and disease status. *[Guide (p.111)]*		X				
1801	Animal handling (observed by the IACUC inspection team) is appropriate to the species.		X				
1802	Room logs confirm that daily observation of each animal, as well as cage cleaning, feeding, and watering are performed at appropriate intervals. *[1200.07(7.c)]*		X				
1803	Special procedures (e.g., diet or water scheduling/restriction, prolonged restraint, etc.) are conducted as described in the IACUC approved protocols based on IACUC inspection team observations. *[1200.07 (Appendix D-1a); PHS (IV.C.1); Guide (p. 27-33)]*		X				
Housing – Primary Enclosures								
1804†	Primary enclosures, cages, and shelters are appropriate (in terms of size, construction, floor space, height, etc.) for the species housed. *[9 CFR (Part 3, Standards); Guide (p. 51-57 and 55-63; the Ag Guide]* Note: • The recommended minimum rabbit cage height is16 inches; rabbit cages that are less than 16 inches in height may be used if the IACUC has determined through performance assessments that the cage is sufficient to meet the behavioral, physical, and physiological needs of the animal. *[Guide (p.58-59)]* • The recommended minimum floor space for a female mouse + litter is 51 in^2; trio breeding may be appropriate in a cage providing 75-82 in^2 of floor space; the IACUC should make this determination based on the outcome of performance based standards. *[Guide (p.56-58)]*		X				
1805‡	The primary enclosure allows the animal to express natural postures, turn around, access food and water, and rest away from urine and feces. *[Guide (p.56)]*		X				
1806	The primary enclosures (cages, tanks, pens, stalls, etc.) and accessories are clean, in good condition, and are free of rust and sharp edges; the enclosure provides safe species appropriate housing. *[Guide (p. 51)]*		X				
1807‡	Outdoor housing provides protection from extreme weather, conditions, the opportunity to retreat, and is adequately ventilated. *[Guide (p. 54-55)]*	X					
1808	Procedural laboratories that house animals for more than 12 hours meet the minimum standards for housing. *[1200.07 (Appendix E-3 b)]*	X					

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Population Management							
1809	Animal records (e.g., cage cards) include the following information, as appropriate *[Guide (p. 75-76); 9 CFR (2.35)]*: • Source of animals • Strain or stock (including genotype using standard nomenclature where applicable) • Name and contact information for PI • Protocol number • Pertinent dates (e.g., acquisition by facility, birth) • Number of individuals per group, when identified in groups • Age or weight • Gender • Individually identifiable features (e.g., markings, tattoos, ear • tags, neck chains, implanted microchips, etc.)		X				
1810	The IACUC inspection team determined that animal records are readily available, appropriately detailed, properly maintained, and accompany animals when transferred to another institution. *[Guide (p. 75-77)]*	X					
Behavioral Management							
1811	The IACUC inspection team determined that the environmental enrichment program is appropriate to the species, ages, and number of animals housed and is beneficial to and safe for the animals. *[Guide (p. 52-54)]*		X				
1812	Animals are housed in compatible social groups as appropriate; socially housed animals are able to escape or hide from aggressive animals, and have ready access to food and water. *[Guide (p. 51-60;63-65)]*		X				
1813	The IACUC inspection team reviewed the records of singly housed animals; *Guide* recommendations for singly housed animals are being followed. *[Guide (p. 64)]*	X					
1814	Based on the behavior observed by the IACUC inspection team, the animals are appropriately habituated to routine husbandry and experimental procedures. *[Guide (p. 64-65)]*		X				
Food							
1815	Each animal is fed uncontaminated, palatable, high quality food using a feed schedule and methods (that considers caloric management, delivery, and sanitation) appropriate to the species. *[Guide (pg. 65-67)]*		X				
Water							
1816	Each terrestrial animal has ready access to potable drinking water (quality based on periodic assessment) and the water distribution system is clean and appropriate to the species. *[Guide (p. 67-68)]*		X				
1817	For aquatic animals, the water quality is appropriate for the species. *[Guide (p. 78-79, 85)]*	X					
1818‡	In aquatic systems, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use. *[Guide (p. 78, 86)]*	X					
1819‡	The biofilter of the aquatic life support system is of adequate size to process the bioload. *[Guide (p 80)]*	X					

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Bedding							
1820	The bedding present in primary enclosures (where appropriate) is consistent with the species, facilitates good health, and meets scientific requirements. *[Guide (p. 68-69)]*		X				
Sanitation							
1821	Cleaning implements are designated for specific rooms or for areas at similar risk of contamination and are in good repair. *[Guide (p. 72)]*		X				
1822	Primary enclosures (including substrates and cage components), animal holding rooms, support spaces, etc. are cleaned and disinfected on a regular schedule consistent with the use of the area and nature of contamination. *[Guide (p 70 -72)]*		X				
1823	The effectiveness of sanitation methods/procedures are assessed and documented. *[Guide (p. 73)]*		X				

C. Animal Procurement and Transportation

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1850	Animals being transported are appropriately restrained, secured, and covered, to protect the health and safety of the animals and humans (passersby as well as personnel involved in the work with the animals), to minimize stress on the animals, and to ensure animal biosecurity. *[1200.07(Appendix E-3a (15)); Guide (p. 107-109); 9 CFR (Part 3. Standards)]*		X				
1851	Promptly on receipt, animals are inspected by qualified personnel and moved to housing appropriate to the protocols for which they have been ordered. *[1200.07 (7.b(3)); Guide (p. 107-109)]*		X				
1852	The condition of animals on arrival indicates that transportation was consistent with USDA regulations and humane practices. *[Guide (p.107)]*		X				

D. Preventive Medicine

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1900	Based on the observations of the facility inspection team, animals are separated by species, source, health status, intended use (as appropriate) and after receipt, the animals are allowed a stabilization period. *[Guide (p. 109-112)]*		X				

E. Waste Disposal

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
1950	Conventional, biological, and hazardous wastes are regularly collected, stored and disposed of through the use of safe handling and processing practices. *[Guide (p. 73-74)]*		X				
1951	Waste receptacles are leak-proof, labeled, cleaned regularly, and have tight-fitting covers. *[Guide (p. 73)]*		X				
1952‡	Hazardous wastes are rendered safe before removal from facility. *[Guide (p. 73-74)]*		X				

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1953	Appropriate containers for sharps disposal are readily available in locations in which sharps are used, and are no more than 2/3 to 3/4 full. *[Guide (p. 74)]*		X				
F. Pest Control							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2000	A humane, effective, and documented pest prevention and control program (that includes rodents and insects) is in place; there is no evidence of pests in the facility. *[Guide (p. 74)]*		X				
2001	When it is necessary to use pesticides in animal holding areas, investigators are consulted in advance of pesticide use. *[Guide (p. 74)]*		X				
G. Medical Supplies							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2050	Non-pharmaceutical grade compounds identified during the inspection were confirmed to be associated with an IACUC approved protocol. *[PHS (FAQ F.4); Guide (31)]*		X				
H. Emergency, After Hours, Weekend, and Holiday Care							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2100	The review of log sheets confirm that animals are cared for by qualified personnel on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74); 9 CFR (2.33(b))]*		X				
2101‡	Posted contact information for veterinary staff and veterinary care entries in logs confirm that emergency veterinary care is available and provided as needed after hours, on weekends and holidays, as well as on regular weekdays. *[Guide ((p. 74;114); 9 CFR (2.33(b))]*		X				
2102	Telephone numbers of key personnel are readily accessible to police and fire agencies at all times. *[Guide (p. 74)]*		X				
I. Other Observations							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2150							

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IV. Veterinary Medical Care

A. General

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2200	Animals are observed at least daily for signs of illness, injury or abnormal behavior by trained personnel. *[Guide (p. 112)]*		X				
2201	Visits by part-time veterinarians are documented in a log showing the date and time of each visit. *[1200.07 (Appendix E-2.f(9))]*		X				

B. Surgery

		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2250	The IACUC inspection team determined that the recommendations of the *Guide* are followed for non-survival surgery (the surgical site is clipped, the surgeon wears gloves, the instruments and the surrounding area are clean). *[Guide (p. 118)]*						X
2251	The IACUC inspection team determined that aseptic technique is used for all survival surgical procedures, and includes appropriate preparation of the animal (shaving and disinfection of the surgical site), preparation of the surgeon (scrubbing, use of sterile glove, gowns, etc.), and use of aseptic operative techniques; the aseptic technique procedures are appropriate for the species used. *[Guide (p. 118-119)]*						X
2252	The IACUC inspection team determined that all surgical instruments and implants used in survival surgery are sterilized by steam, gas, or approved chemicals. Note: Alcohol is not a sterilant or a high-level disinfectant. *[Guide (p. 119)]*						X
2254	The IACUC inspection team observed that for multiple consecutive rodent surgeries, personnel using hot bead sterilizers or liquid chemical sterilants for instrument sterilization take appropriate precautions to prevent thermal or chemical burns. *[Guide (p. 119)]*						X
2255	The IACUC inspection team confirmed that the operating area is cleaned and disinfected prior to major survival surgery. *[Guide (p. 117)]*						X
2256	The IACUC inspection team confirmed that appropriate intraoperative monitoring of anesthetic depth and physiological parameters is performed and documented by personnel. *[Guide (p. 119)]*						X
2257	The IACUC inspection team confirmed that postoperative monitoring and care of appropriate intensity and frequency (includes anesthesia recovery, pain management, management of physiologic needs, assessment of overall well-being, wound healing, suture removal, etc.) was provided and documented by trained personnel. *[Guide (p. 119-120)]*						X

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C. Pain, Distress, Analgesia and Anesthesia							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2300‡	Drug storage and control practices comply with federal regulations for human and veterinary drugs *[Guide (p. 115)]*		X				
2301‡	Analgesics and anesthetics (as well as other drugs) are used within their expiration date. *[Guide (p. 122)]*		X				
2302	Procedures for acquiring, using and storing anesthetics and analgesics are compliant with legal and safety standards. *[Guide (p. 115; 122)]*		X				
2303‡	Observation and/or record review indicates that before surgery begins, personnel ensured a surgical plane of anesthesia is attained. *[Guide (p. 122)]*						X
2304	The IACUC inspection team determined that neuromuscular blocking agents are used in a humane and appropriate manner in accordance with the IACUC approved protocol. (*[Guide (p. 122-123)]*		X				

D. Euthanasia							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2350	Personnel are competent in performing euthanasia methods that are appropriate to the animal's age and species and are consistent with AVMA Guidelines. Alternate methods of euthanasia, if used, are approved by the IACUC. *[Guide (p. 124); 9 CFR (2.31(d)(1)(xi))]*		X				
2351‡	Personnel confirm animal death after the euthanasia procedure. *[Guide (p.124)]*		X				

E. Other Observations							
		Not Applicable	Acceptable	Approved Departure	Minor Deficiency	Significant Deficiency	Could Not Evaluate
2400							

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE PROGRAM AND FACILITIES
Part 2 -- Table of Deficiencies and Departures

This form is for documenting the details about the observations noted in the checklists (Part 1, Sections A and B). Each deficiency, minor or significant, must be entered according to Instructions 2 and 3, below. Each "approved departure", as defined by OLAW, must be entered according to Instruction 4, below. The IACUC may also document on this form, at its discretion, other observations that are not deficiencies, and details about "deviations" that are not "departures", as defined by OLAW – these may be useful in addressing concerns raised by accreditation or regulatory agencies, or for monitoring purposes.

Instructions:

1) Enter identifying information in the header above:
   Double click in the header area.
   Then enter text after each ":"
      (Note: The "Date of Last Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities were last completed. Federal regulations require that a new evaluation be completed no later than 6 months after the last evaluation.)
   Double click in the document area to return to the main body of Form 1.

2) Enter deficiencies with corrections that were still pending on the last report. Copy onto this form each item that was reported on Form 2 of the last semiannual evaluation, for which the correction was not yet completed when the last report was signed:
   Enter the date the deficiency was first noted in a semiannual evaluation.
   If the IACUC determines that a change in the scheduled date of correction is appropriate, ~~strike out the previously approved date and~~ add the new date below it.
   Enter the actual date when the correction of the deficiency was completed. If the work is not yet complete, leave the "Actual date of completion" blank, but include in the description any relevant information about progress to date.

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Note: USDA requires the IACUC to report any failure to adhere to the plan and schedule for correction that results in a significant deficiency remaining uncorrected beyond the correction date set by the IACUC. The report must be submitted in writing within 15 business days of missing the correction date set by the IACUC, through the IO, to the Animal and Plant Health Inspection Service (APHIS) and any Federal agency funding the activity involved. Therefore, for the IACUC to change the correction date of a significant deficiency, it must review the justification for the change and approve a new correction date at a convened committee meeting prior to the original correction date.

3) Enter each new deficiency noted on Form 1 (Checklist), Parts A and B, of this report:
The date the deficiency was first noted.
The Part (A or B) and Item # on Form 1 to which it applies.
When applicable, indicate the location where the deficiency was noted.
A description of the specific deficiency -- Include sufficient detail for an outside observer to recognize when it has been corrected), a description of any underlying programmatic or systemic conditions that may have led to the deficiency, and a description of the plans both for correcting the deficiency and for addressing underlying factors so as to prevent recurrence. *[PHS (IV.B.3)]* Be sure to include the name of the individual who will be responsible for overseeing progress on the corrective action, on behalf of the IACUC. (The table will expand to accommodate the text entered.)
The severity of the deficiency (Minor [M] or Significant [S]), as indicated on Form 1.
The scheduled date of correction – enter the date by which the IACUC has determined that the correction should be completed.
The actual date when the correction of the deficiency was completed (leave blank if the work is not yet complete.)

4) Enter each "departure" from PHS Policy, including the provisions of the *Guide*, that has been approved by the IACUC. *[PHS (IV.B.3)]*

For any deviation from a general standard described in the *Guide*, the following series of test questions may be applied to determine whether the deviation is considered a "departure" by OLAW:

1. Does the Guide describe the general standard as a "May" standard? If so, this deviation from the general standard is NOT a "departure". Otherwise, for any "Should" or "Must" standard, proceed to the next question.

2. Does the Guide include an explicitly stated exception that allows for the deviation? If so, this deviation from the general standard is NOT a "departure. Otherwise, proceed to the next question.

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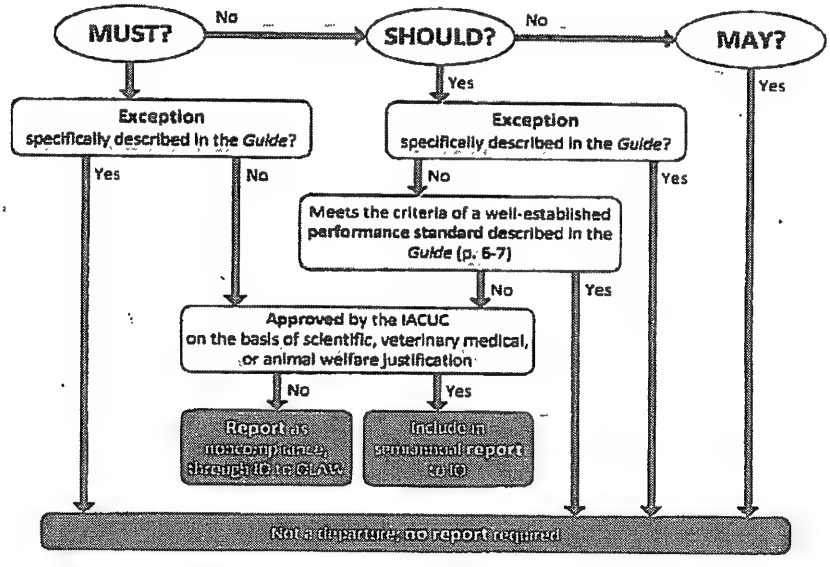
3. Does the deviation meet a well-established performance standard for a "Should" standard, according to locally-defined and continuously monitored performance measures? If so, this deviation from the general standard is NOT a "departure". Otherwise, it IS a "departure", and may be approved by the IACUC only if justified on scientific, veterinary medical, or animal welfare grounds.

The test questions above are summarized in the following flow chart:



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For approved departures that are documented in Appendix 9 of an IACUC-approved ACORP, simply attach a copy of Appendix 9. (The Official Date of Approval in the header must be included, but be sure to redact the name of the PI and the protocol number assigned by the IACUC.) Enter below the table here the total number of Appendix 9 pages attached.

For approved departures that are not documented in an Appendix 9, enter the information into this form as follows:
For "Original Date Noted", enter the date of the IACUC meeting at which the departures were reviewed and approved.
[1200.07 (8.f(1)(d)2-3); PHS (IV.B.3) 9 CFR (2.31 (c)(3)); and Guide (p. 9]
If the departure relates to a specific item on Form 1, enter the Part (A or B) and Item # to which it applies.
If applicable, indicate the location to which the departure applies.
A description of the departure – include a summary of the grounds for granting approval for the departure.
Mark the "D" category, to indicate that the item details a departure.
Enter "N/A" in the columns for the "Scheduled Date of Correction" and the "Actual Date of Correction".

5) Press "Tab" in bottom right cell to add rows to the table.

Original Date Noted	Form 1 Part	Form 1 Item #	Location	Descriptive Details	Category M	Category S	Category D	Scheduled Date of Correction	Actual Date Of Correction
12/11/18			(b)(6)	Replace burned out ligh (b)(6) ▶Person responsible for overseeing correction: VMU Supervisor	X			1/31/19	1/9/19
12/11/18				Sand and Paint Vent (b)(6) ▶Person responsible for overseeing correction: VMU Supervisor	X			1/31/19	1/15/19
12/11/18				Change air filte (b)(6) ▶Person responsible for overseeing correction: VMU Supervisor	X			1/31/19	1/14/19

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12/11/18			(b)(6)	Caulk around exposed pipe [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/10/19
12/11/18				Repair cracked ceiling [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/24/19
12/11/18				Clean ve[redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/15/19
12/11/18				Repair baseboards/remove tape [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/11/19
12/11/18				Repair broken floor tile [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/11/19
12/11/18				clean inside light cover [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/9/19
12/11/18				replace reefer door seal/sweep [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	
12/11/18				clean inside light cover [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/10/19
12/11/18				repair water faucet pressure [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	
12/11/18				replace burned out light bulbs [redacted] ► Person responsible for overseeing correction: [redacted]	X			1/31/19	1/9/19

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VA SEMIANNUAL EVALUATION
of the
INSTITUTIONAL ANIMAL CARE AND USE
PROGRAM AND FACILITIES

Part 3 – Post-Review Documentation

Instructions (The "▶" symbols indicate required information):

1) Enter identifying information in the header above:
Double click in the header area.
Then enter text after each ":"
(Note: The "Date of Semiannual Evaluation" is considered to be the date by which both the Review of the Program and the Inspection of the Facilities are completed.)
Double click in the document area to return to the main body of Form 1.

2) ▶Enter the date of the most recent previous Semiannual Evaluation: June 14, 2018

3) Enter the names of all voting members of the IACUC, and identify the member who fills each required role on the committee, in the table in Section D, below. If any alternate members have been appointed, enter the name of each alternate member in the square brackets (e.g., "[Alt: John Smith]") below the name of each primary member for whom the alternate may serve. Only one member, the primary or the designated alternate, should sign in any one row of the table. (Press "Tab" in bottom right cell to add rows to the table.)

4) Complete Sections A-F, below.

A. SUMMARY OF SEMIANNUAL EVALUATION. Summarize the results of this semiannual evaluation, including an analysis of the implications of the results for the animal research program as a whole. The summary should:

- Note the total number of "departures" from PHS policy, including the provisions of the *Guide*, that have been approved by the IACUC.
- Provide summary overviews of the programmatic and facility deficiencies
  - If there were no deficiencies, include a statement to this effect in the report.
  - If deficiencies were identified, evaluate the overall number and severity of the deficiencies, and what the number and severity indicate about the quality of the program and facilities (refer to the complete list provided in Part 2 – Table of Deficiencies and Departures).
- Comment on any patterns or trends suggested by the observations during this semiannual evaluation and also in the light of previous semiannual reports.

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- Acknowledge any laudable aspects of the overall animal care and use program (i.e., related to the program, facility, or personnel).

- Provide a concluding paragraph that: (1) assesses the institution's overall compliance with applicable PHS Policy, the *Guide*, the AWA, and VA Policy; (2) provides recommendations to the IO; and (3) highlights any other pertinent information the IO should be made aware of.

B. DOCUMENTATION of MINORITY OPINION(S). *Any participant in the semiannual evaluation who wishes to provide a minority opinion MUST be allowed to do so [1200.07 (8,f(1)(d)(2); PHS (IV.E.1.d); 9 CFR (2.31(c)(3))].* Did any participant submit a minority opinion?

_____ Yes _____X_____ No If "yes", fill out section E below.

C. Statement of AAALAC Accreditation *[PHS (IV.B.3)].* Are all VA animals housed or used only in facilities that are part of an AAALAC accredited program?

__X__ Yes. If yes, describe the accreditation as indicated below.

Identify the AAALAC accredited program: South Texas Veteran Health Care System

Give the date of the most recent achievement of Full Accreditation: **June 14, 2016**

____ No. If no, describe the components that are not Fully Accredited, as indicated below.

If VA animals are housed or used at an affiliate institution that is not AAALAC accredited,

Identify the affiliate:

Give the date on which the CVMO approved this arrangement:

If VA animals are housed or used at an institution where the AAALAC accreditation status is other than Full Accreditation,

Identify the institution:

Give the current accreditation status:

Describe briefly the current status of the institution in the process of regaining full accreditation:

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D. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS. *A majority of all voting members (not merely a majority of a quorum) must approve and sign the report [1200.07 (8,f(1)(e)); 9 CFR (2.31(c)(3))]. The report must be completed within one month of the date of the semiannual evaluation to facilitate timely progress on any corrective actions required.*

The undersigned verify that we
1) have reviewed and approved Forms 1 (Checklist, Parts A and B) and 2 (Table of Deficiencies and Departures),
2) have read any minority opinions appearing in item E of this report, and
3) hereby authorize IACUC representatives to review this report with the Medical Center Director:

TYPED NAME	ROLE ON IACUC	SIGNATURE	DATE
(b)(6)	(b)(6)	(b)(6)	1/11/2019
(b)(6)			1/11/2019
(b)(6)			1/11/2019

E. MINORITY OPINION(S). If part B is checked "yes", provide the typed minority opinion(s) here:

F. COMMUNICATION WITH DIRECTOR OF THE FACILITY. After a majority of all voting IACUC members approve the report and indicate their approval (in Section D, above) by signatures next to their typed names and roles on the committee, *the report must be discussed personally with the facility Director by at least one voting member of the IACUC, representing the committee. It is recommended that the Attending Veterinarian and the IACUC Chair meet with the Director (any voting member of the IACUC who wishes to participate must be allowed to do so). It is a best practice for the ACOS for R&D and/or the AO for R&D to attend as well. After the meeting, the Director must sign the reporting indicating that he/she has reviewed it. [1200.7(8,f(1)(e))].* **Note: the Director's signature only indicates awareness of the contents of the report, and does not imply agreement with the report or satisfaction with the corrective measures proposed. The report may not be altered after it has been signed by a majority of the voting IACUC membership, but any disputed items may be discussed in a cover memo.**

Certification: By my signature, I acknowledge receipt of this report, and verify that I have personally discussed its contents with the representatives of the IACUC.

Typed Name of Director	Signature	Date
(b)(6)	(b)(6)	1-18-19

▶Name of Medical Center: South Texas Veterans Health Care System Version 02/28/13
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G. FINAL PROCESSING

A signed copy of the complete report (including Parts 1, 2, and 3) must be sent through the ACOS/R&D and Medical Center Director to the CVMO within 60 days of the date of approval and signature by a majority of the voting IACUC members. The R&D Committee should review the approved report as an item of business, but R&D approval is not required before submission of the final document to the CVMO. Send a copy including all signatures as a hard copy to Dr. (b)(6) (b)(6) A[redacted] GA 30033, or as an email attachment to (b)(6) va.gov and (b)(6) @va.gov. The original must be retained for at least three years.

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

Location/Building/Facility:	STVHCS, ALMD, Veterinary Medical Unit

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

- HVACs for VMU uses 100% Outside air
- HVAC Systems use filtered air, filters are checked monthly and are changed quarterly
- Chilled water and re-heat coils are used, 2-3 rooms/reheat control, adjusted towards atmospheric temperature
- If re-heat coil fails, alarm is set off in Engineering/Energy Systems section. During winter months, re-heat coil fails in the open position and closed during the summer months.
- Room air pressure is monitored, yearly, by the STVHCS Safety Office.
- Animal Holding Room temperatures are monitored by Energy Systems and the Edstrom Watchdog System…if Watchdog is alarmed, telephonic notification is sent to VMU Supervisor or his representative.

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however, measurements may be left at the discretion of the institution.* Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	+	15	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	9	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	10	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	13	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	+	10	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	20	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	16	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	11	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	8	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	10	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	11	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	9	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	9	12/2018

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	17	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	11	12/2018
	Animal Holding Room	68-72°F	Y	64°F & 74°F	N	-	12	12/2018
	Procedure Room	68-72°F	Y	64°F & 74°F	N	-	11	12/2018
	Procedure Room	68-72°F	Y	64°F & 74°F	N	+	12	12/2018
	Procedure Room	68-72°F	Y	64°F & 74°F	N	+	12	12/2018
	Procedure Room	68-72°F	Y	64°F & 74°F	N	+	11	12/2018
	Procedure Room	68-72°F	Y	64°F & 74°F	N	+	12	12/2018

[Create additional rows by pressing TAB in the bottom-right box.]

Copy and repeat the Description and Table for each location, including all satellite housing locations.

Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

(1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
(2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
(3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
(4) Indicate water type, e.g., fresh, brackish, or marine.
(5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
(6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
(7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

Part I

Location (1)	Species (2)	System Design					
		Group / Individual (3)	Water Type (4)	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc.*) should be available for review.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:

(1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).

(2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

Part II

Monitoring *Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)*									
Location (from Part I)	**Temperature**	**Salinity**	**pH**	**NH_4**	**NO_2**	**NO_3**	**Dissolved O_2**	**Total Dissolved Gases**	**Other. Please List (2):**

Note: This information may be provided in another format, provided that all requested data is included.

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Mice	Allentown – Ventilated 11"x7"x5" = 75sq in	5	Guide	Polysulfone and stainless-steel components with polysulfone water bottle & neoprene & stainless-steel sipper tube
Mice (breeders)	ACS – Ventilated 13.5"x7" = 94.5sq in floorspace	3 Adults plus pups	Guide	Polysulfone and stainless-steel components with polysulfone water bottle & neoprene & stainless-steel sipper tube
Rat	ACS – Ventilated 12.1"x14.1" = 175sq in floorspace	3	Guide	Polysulfone and stainless-steel components with polysulfone water bottle & neoprene & stainless-steel sipper tube

*For aquatic species, provide tank volume.
**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Micro-environment				
Solid-bottom cages (static)				
Solid-bottom cages (IVC)	Cage/Tunnel Washer/Detergent	every 2 weeks	Cani, Inc., CP710	
Suspended wire-bottom or slotted floor cages				
Cage lids	Cage/Tunnel Washer/Detergent	every 2 weeks	Cani, Inc., CP710	
Filter tops	Cage/Tunnel Washer/Detergent	every 2 weeks	Cani, Inc., CP710	
Cage racks and shelves	Cage Washer/Detergent	every 6 months or as needed	Cani, Inc., Complete IV	
Cage pans under suspended cages				
Play pens, floor pens, stalls, etc.				
Corrals for primates or outdoor paddocks for livestock				
Aquatic, amphibian, and reptile tanks and enclosures				

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Feeders	Cage/Tunnel Washer/Detergent	every 2 weeks	Cani, Inc., CP710	
Watering devices	Cage/Tunnel Washer/Detergent	every 2 weeks	Cani, Inc., CP710	
Exercise devices and manipulanda used in environmental enrichment programs, etc.				
Transport cages				
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)				
Euthanasia chambers	Cage/Tunnel Washer/Detergent	Daily	Cani, Inc., CP710	
Macro-Environment				
Animal Housing Rooms:				
Floors	Daily		Quatricide-PV15	
Walls	Monthly		Quatricide-PV15	
Ceilings				

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Ducts/Pipes				
Fixtures	Daily		Sani-Cloths	
Corridors:				
Floors	Weekly		Quatricide-PV15	
Walls	Weekly		Sani-Cloths	
Ceilings				
Ducts/Pipes				
Fixtures	Weekly		Sani-Cloths	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Daily		Quatricide PV15	
Walls	Weekly		Quatricide PV15	
Ceilings				
Ducts/Pipes	Weekly		Sani-Cloths	
Fixtures	Daily		Sani-Cloths	
Implements (note whether or not shared):				
Mops	Monthly		Tide Detergent	
Mop buckets	Weekly		Cani, Inc., CP710	

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Aquaria nets				
Other				
Other:				
Vehicle(s)				
Other transport equipment (list)				

*Please provide chemical, not trade name.

Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, *etc.*). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
STVHCS, ALMD VMU	(b)(6)	Cage Washer	Emergency "off" button; labeled exit door, de-energizing cord on both sides, instructional signage	Guarantee 180-degree hot water rinse; Cani Inc., Complete IV; temperature-sensitive tape used during initial cycle
STVHCS, ALMD VMU		Tunnel washer	Emergency "off" button; instructional signage	Guarantee 180-degree hot water rinse; Cani, Inc. CP710; temperature-sensitive tape used daily; caging tested semi-annually
STVHCS, ALMD VMU		Autoclave	Emergency "off" button; lock-out key	D.A.R.T. testing, monthly

[Create additional rows by pressing TAB in the bottom-right box.]

Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

Location: STVHCS, ALMD, Veterinary Medical Unit (VMU)

Room Type[a]	Light Intensity Range	Lighting Fixture Construction Features[b]	Photo-period (hrs)[c]	Photoperiod and Lighting Control	Override Mechanisms (if applicable)
Rodent Holding Rooms	130-300 lux	Ceiling mounted	12/12	Automatic via mechanical timer	Mechanical timer can be manipulated as needed
Surgery	Not measured	Recessed; arm-mounted, water resistant	N/A	N/A	N/A
Necropsy	Not measured	Recessed; arm-mounted, water resistant	N/A	N/A	N/A
Tunnel/Cage Wash Room	Not measured	Recessed	N/A	N/A	N/A
Procedure Rooms	Not measured	Recessed	N/A	N/A	N/A

[Create additional rows by pressing TAB in the bottom-right box.]

[a] A list of each room is not needed; group or cluster rooms by species or function
[b] Include such features as water resistance, red lighting, *etc.*
[c] Note if light cycle inverted/reversed.

Repeat Location and Table as necessary for each location, including satellite housing locations.

Appendix 17: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary **(Appendix 11)** and Lighting Systems Summary **(Appendix 16)**.

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft^2 or m^2) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes

[Create additional rows by pressing TAB in the bottom-right box.]